

THE DESIGN AND MULTI-METHOD EVALUATION OF A PILOT PRAGMATIC RANDOMISED CONTROLLED TRIAL OF AN EXERCISE ASSISTED REDUCTION OF SMOKING INTERVENTION AMONG SOCIOECONOMICALLY DISADVANTAGED SMOKERS

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ABSTRACT

Background: Smoking contributes to health inequalities and there is a need to focus interventions on the disadvantaged. Abrupt quitting is widely advocated, but assisted 'reduction' may be an option for those not ready to quit. Physical activity acutely reduces cigarette cravings and withdrawal symptoms, and may increase long-term cessation and reduce weight gain. This thesis reports on the multi-method evaluation of an intervention delivered by Health Trainers (HTs) and a pilot randomised controlled trial of the Exercise Assisted Reduction then Stop (EARS) intervention for disadvantaged smokers who are not ready to quit, but do wish to reduce, without nicotine replacement therapy. This programme of research aimed to evaluate four aspects of the EARS trial: 1) Recruitment, 2) Study attrition, 3) Main quantitative outcomes, and 4) Intervention fidelity.

Methods: 1) Recruitment: Smokers were recruited through mailed invitations from three primary care practices (62 participants) and one National Health Stop Smoking Service (SSS) database (31 participants). Six other participants were recruited via a variety of other community-based approaches. Data were collected through questionnaires, field notes, work sampling, and databases. Chi-squared and t-tests were used to compare baseline characteristics of participants. 2) Study Attrition: Disadvantaged smokers who wanted to reduce but not quit were randomised (N=99), of whom 61 (62%) completed follow-up assessments at 16 weeks. Univariable logistic regression was conducted to determine the effects of intervention arm, method of recruitment, and participant characteristics (socio-demographic factors, and lifestyle, behavioural and attitudinal characteristics) on attrition, followed by multivariable logistic regression on those factors found to be related to attrition. 3) Main quantitative

outcomes: Data at 16 weeks were collected for various smoking and physical activity outcomes. Primary analyses consisted of an intention to treat analysis based on complete case data. Secondary analyses explored the impact of handling missing data, examining different methods including last baseline observation carried forward, last observation carried forward, and multiple imputation. 4) Intervention fidelity: Three researchers scored a total of 90 audio recorded consultations for 30 different participants split between three HTs delivering the intervention. Delivery was scored using a 0-6 likert scale for 12 different processes identified as being fundamental to the intervention.

Results: 1) Recruitment: Depending on the intensity and time invested in following up those who did not initially respond to a letter, we randomised between 5.1–11.1% of those invited through primary care and SSS, with associated researcher time to recruit one participant varying from 18 –157 minutes. Recruitment rates were similar for invitations sent from primary care and SSS. Despite substantial time and effort, only six participants of our total of 99 were recruited through a wide variety of other community-based approaches, with an associated researcher time of 469 minutes to recruit one participant. Targets for recruiting a disadvantaged population were met, with 91% of the sample in social classes C2–E, and 41% reporting moderate to severe depression or anxiety. However, we under-recruited single parent smokers. Chi squared tests revealed that those recruited from the SSS database were more likely to respond to an initial letter, had used cessation aids before and had attempted to quit in the past year. Overall, initial responders were more likely to be physically active than those who were recruited via follow-up telephone calls. No other demographic or behaviour characteristics were associated with recruitment approach or intensity of effort. Qualitative feedback indicated that

participants had been attracted by the prospect of being assigned to an intervention that focused on smoking reduction rather than abrupt quitting. 2) Attrition: Participants with low confidence to quit, and who were undertaking less than 150 minutes of moderate and vigorous physical activity per week at baseline were less likely to complete the 16-week follow-up assessment. Exploratory analysis revealed that those who were lost to follow-up early in the trial (i.e., by 4 weeks), compared with those completing the study, were younger, had smoked for fewer years and had lower confidence to quit in the next 6 months. Participants who recorded a higher expired air carbon monoxide reading at baseline were more likely to drop out late in the study, as were those recruited via follow-up telephone calls. Multivariable analyses showed that only completing less than 150 minutes of physical activity retained any confidence in predicting attrition in the presence of other variables. 3) Main quantitative outcomes: Compared with controls, intervention smokers made more quit attempts (36 v 10%; Odds Ratio 5.05, (95% CI: 1.10; 23.15)), and a greater proportion achieved $\geq 50\%$ reduction in cigarettes smoked (63 v 32%; 4.21 (1.32; 13.39)). Post-quit abstinence measured by exhaled carbon monoxide at 4 week follow-up showed promising differences between groups (23% v 6%; 4.91 (0.80; 30.24)). No benefit of intervention on physical activity was found. Secondary analyses suggested that the standard missing data assumption of 'missing' being equivalent to 'smoking' may be conservative resulting in a reduced intervention effect. 4) Fidelity: All three HTs demonstrated high levels of skill in delivering a client-centred motivational interviewing based intervention. Processes relating to physical activity were not delivered as well as those relating to smoking behaviour. Processes related to social support were poorly

delivered. There was little variation between individual HT scores and the scores of the researchers completing the scoring.

Conclusions: 1) Recruitment: Mailed invitations, and follow-up, from health professionals was an effective method of recruiting disadvantaged smokers into a trial of an exercise intervention to aid smoking reduction. Recruitment via community outreach approaches was largely ineffective. 2) Study attrition: The findings indicate that those who take more effort to be recruited, are younger, are heavier smokers, have less confidence to quit, and are less physically active require more effort to be retained once recruited . 3) Main quantitative outcomes: A smoking reduction intervention for economically disadvantaged smokers which involved personal support to increase physical activity appears to be more effective than usual care in achieving reduction and may promote cessation. The effect does not appear to be influenced by an increase in physical activity. 4) Intervention fidelity was deemed to be successful overall. Key areas for improvement have been identified, including recommendations for future training as well as methodological implementation.

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ACKNOWLEDGEMENTS

Firstly, I would like to acknowledge my friends and family who have supported me throughout the last however many years – even though they still have no idea what exactly it is I do, their support has been there regardless! Thank you.

I would like to thank all the co-applicants on the EARS project: Colin Greaves, Rod Taylor, Colin Green, Fiona Warren, Rebecca Kandiyali, Paul Aveyard, Richard Ayres, Richard Byng, John Campbell, Michael Ussher, Susan Michie, and Robert West for all of their input and advice whilst working on the EARS study. I have learned from all of you in many different ways and it has been a privilege to experience working as part of such a team. My particular thanks go to Fiona Warren for her support with developing the statistical analyses, and to Colin Greaves for the support in developing the qualitative aspects of the work. I would also like to thank Marcela Haasova for her help with the baseline data, Pippa Griew for her guidance on working with accelerometry data, and Jeff Lambert for his help with assessing intervention fidelity.

To the three researchers/Health Trainers, Julie Lloyd, Maggie Kelly, and Mel Fairbairn, I offer my deepest gratitude as without your tireless efforts none of the project would have been possible. Thanks also go to Naomi Southern for her administrative support throughout the project and helping to keep me organised.

Thanks to all the GP practices, the Stop Smoking Services (in particular Russ Moody and Mandy Luffman), Plymouth Public Health, the staff at the Cumberland Centre, and all the community organisations involved for all of their help and support in so many aspects of the EARS study.

Special thanks go to all the participants who gave their time to be part of the EARS study and make this important research possible, and hope they gained as much from their participation as we did.

Finally, special appreciation is reserved my supervisor, Professor Adrian Taylor, without whom none of this would have been possible. His support, both professionally and personally, has been relentless and has shaped the course of my life over the last six years. With his support I have achieved things I never thought possible, and I look forward to the next chapter – trials, challenges, and all!

PUBLICATIONS AND CONFERENCE PROCEEDINGS

PUBLICATIONS

Thompson, T. P., Greaves, C. J., Ayres, R., Aveyard, P., Warren, F. C., Byng, R., Taylor, R. S., Campbell, J. L., Ussher, M., Green, C. Michie, S., West, R., Taylor, A. H. An exploratory analysis of the smoking and physical activity outcomes from a pilot randomised controlled trial of an exercise assisted reduction to stop (EARS) smoking intervention in disadvantaged groups. *Nicotine & Tobacco Research* 05/2015; DOI:10.1093/ntr/ntv099

Thompson, T. P., Greaves, C. J., Ayres, R., Aveyard, P., Warren, F. C., Byng, R., Taylor, R. S., Campbell, J. L., Ussher, M., Michie, S., West, R., Taylor, A. H. Lessons learned from recruiting socioeconomically disadvantaged smokers into a pilot randomized controlled trial to explore the role of Exercise Assisted Reduction then Stop (EARS) smoking *Trials* 02/2015; 16(1-1):1. DOI:10.1186/1745-6215-16-1

Taylor, A. H., Thompson, T. P., Greaves, C. J., Taylor, R. S., Green, C., Warren, F. C., Kandiyali, R., Aveyard, P., Ayres, R., Byng, R., Campbell, J. L., Ussher, M. H., Michie, S., West, R. (2014). A pilot randomised trial to assess the methods and procedures for evaluating the clinical effectiveness and cost-effectiveness of Exercise Assisted Reduction then Stop (EARS) among disadvantaged smokers. *Health Technology Assessment (Winchester, England)*, 18(4), 1–324.

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Under Review

Thompson, T. P., Greaves, C.J., Ayres, R., Aveyard, P., Warren, F.C., Byng, R., Taylor, R.S., Campbell, J.L, Ussher, M., Michie, S., West, R., & Taylor, A.H. *Under review*. Factors associated with study attrition in a pilot randomised controlled trial to explore the role of exercise assisted reduction to stop (EARS) smoking in disadvantaged groups. *BMC Health Services Research*.

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SELECTED CONFERENCE PROCEEDINGS

Thompson, T. P., Greaves, C.J., Ayres, R., Aveyard, P., Warren, F.C., Byng, R., Taylor, R.S., Campbell, J.L, Ussher, M., C. Green, Michie, S., West, R., & Taylor, A.H. An exploratory analysis of the smoking and physical activity outcomes from a pilot randomised controlled trial of an exercise assisted reduction to stop (EARS) smoking intervention in disadvantaged groups. UK Society for Behavioural Medicine Conference, Nottingham, 2nd-4th December, 2014. (ORAL PRESENTATION).

Thompson, T. P., Greaves, C.J., Ayres, R., Aveyard, P., Warren, F.C., Byng, R., Campbell, J.L, Taylor, R.S., Ussher, M., Michie, S., West, R., Green, C. , & Taylor, A.H. The recruitment and retention of low-socioeconomic status smokers in a pilot randomised controlled trial supporting smoking reduction with facilitated physical activity. UKCTAS Early Career Researcher Event, Leeds, 18th June 2014. (ORAL PRESENTATION).

The design and multi-method evaluation of a pragmatic randomised controlled trial of an exercise assisted reduction of smoking intervention among socioeconomically disadvantaged smokers. A one-day symposium for PhD students researching substance (mis)use. The Society for the Study of Addiction, Oxford Brookes University, Oxford, 12th July 2013 (ORAL PRESENTATION).

Thompson, T. P., Aveyard, P., Ayres, R., Taylor, R., Warren, F., Campbell, J., Byng, R., Ussher, M., Michie, S., West, R., Green, C., Greaves, C. & Taylor, A.H. Multiple health behaviour change: how to tackle the linked behaviours of smoking, weight management, and physical activity. Improving public health outcomes: why clusters of lifestyle behaviours matter. The King's Fund, London, 6th March, 2013. (POSTER and ORAL PRESENTATION). An evaluation of the effects of a physical activity intervention for smoking reduction and cessation aid among the 'hard to reach' who don't want to quit. 12th International Sport Sciences Congress 2012, Denizli, Turkey, 12th-14th December 2012 (INVITED SPEAKER).

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Thompson, T. P., Aveyard, P., Greaves, C., Taylor, R., Warren, F., Green, C., Ayres, R., Campbell, J., Ussher, M., Michie, S., West, R., Byng, R., & Taylor, A.H. An exploratory trial to evaluate the effects of a physical activity intervention as a smoking cessation induction and cessation aid among the 'hard to reach': exercise assisted reduction then stop (EARS) (2013). Society for Research on nicotine and

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Adrian H. Taylor, Tom Thompson, Ann Rowlands, Michael Ussher, Paul Aveyard, Richard Ayres, Richard Byng, Rod Taylor, Colin Greaves, John Campbell, Colin Green, Susan Michie, & Robert West (2010).Exercise Assisted Reduction then Stop (EARS) among 'hard to reach' smokers: Trial rationale and design. UK Society for Behavioural Medicine Conference, Leeds, UK, 14th-15th December, 2010 (POSTER PRESENTATION)

ABBREVIATIONS

BCF	Baseline carried forward
BMI	Body Mass Index
CI	Confidence interval
CO	Carbon monoxide
CTIMP	Clinical trial of an investigational medicinal product
EARS	Exercise Assisted Reduction then Stop
FTCD	Fagerström Test for Cigarette Dependence
FTND	Fagerström Test for Nicotine Dependence
GP	General Practitioner
HT	Health Trainer
HTA	Health Technology Assessment
IQR	Interquartile range
ISRCTN	International Standardised Randomised Controlled Trial Number
ITT	Intention to treat
LOCF	Last observation carried forward
LREC	Local Research Ethics Committee
MICE	Multiple imputation chained equations
MVPA	Moderate and vigorous physical activity
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NRT	Nicotine Replacement Therapy
PA	Physical activity
PC	Primary Care
RCT	Randomised controlled trial

ppm	parts per million
RR	Relative risk
SD	Standard Deviation
SES	Socioeconomic status
SSS	Stop Smoking Services
UKCRN	United Kingdom Clinical Research Network

1. INTRODUCTION

The research presented in this thesis takes place within the broader setting of a phase 2 exploratory randomised controlled trial funded by the National Institute of Health's Health Technology Assessment programme. Presented below is the background to both the larger project as well as the issues which are subsequently addressed in this research. This section closes with an over view of the main research findings from the larger randomised controlled trial (RCT). Subsequent chapters then go on to address the additional research being completed within this trial which form the basis of this candidate's PhD submission.

1.1. Background

Health service priorities for helping people to quit smoking focus on identifying a quit date with associated abrupt cessation, involving pharmacological and behavioural support. After one year, only about 4% of those who attempt to quit without support succeed (Hughes, Keely, & Naud, 2004), whereas that figure is almost doubled (7%) with National Health Service (NHS) support in primary care and almost quadrupled (15%) with the support of NHS specialist Stop Smoking Services (Ferguson, Bauld, Chesterman, & Judge, 2005) in the UK (defined by 4 week post quit expired air carbon monoxide (CO) reading of less than 10 parts per million (ppm)). In recent years greater resources have been directed towards helping disadvantaged groups (e.g. unemployed, low-skilled manual workers, people with mental health problems) to quit in an attempt to address growing health inequalities (Bauld, Judge, & Platt, 2007). Smokers from such groups attempt to quit at the same rate as others but their success in quitting is lower (Hiscock, Bauld, Amos, Fidler, & Munafo, 2012), resulting in a growing disparity in prevalence rates, and therefore in consequent health

inequalities. For example, from 2007-2008, among those in social class grades C2-E smoking prevalence rates reduced by only 1.3% compared with 2.3% for grades AB-C1 (West, 2008) in the UK with similar trends in the United States (Secades-Villa et al., 2013) suggesting an need for interventions specifically designed for these groups (Pyatak et al., 2012).

Good quality evidence for the effectiveness of smoking cessation interventions for disadvantaged groups is limited (Bryant, Bonevski, Paul, McElduff, & Attia, 2011; Ranney, Melvin, Lux, McClain, & Lohr, 2006) and further research is needed on how best to both increase intervention reach and smoking cessation success to reduce health inequalities (Murray, Bauld, Hackshaw, & McNeill, 2009). It is likely that a range of options may be needed to increase reach, and to reduce smoking prevalence, such as locating services in community settings with most need, developing roles for NHS outreach workers (e.g., health trainers) (Michie, Rumsey, et al., 2008), and developing complex behaviour change interventions that are specifically designed for disadvantaged groups (Michie, Jochelson, Markham, & Bridle, 2008).

Abrupt cessation is the preferred treatment approach for quitting because, in theory, smokers who cut down prior to quitting may gain greater reward, in the form of greater relief from negative emotions and mood associated with withdrawal, from each cigarette and hence find quitting more difficult (McEwen, Hajek, McRobbie, & West, 2006). Yet, in the English Smoking Toolkit Study, 57% of current smokers reported they were in the process of cutting down (West, 2008) with a variety of approaches being used (Beard, Vangeli, Michie, & West, 2012). While nicotine replacement therapy (NRT) is popular as an aid for smoking reduction, another study revealed that 31% of smokers believed

that sustained use of NRT was 'very' or 'quite' harmful to health (Black, Beard, Brown, Fidler, & West, 2012). Furthermore, stop smoking advisors and managers have expressed concern that combining NRT with smoking may have negative health consequences (Beard, McDermott, McEwen, & West, 2012). There is clearly a need for further research on supporting smoking reduction for those who do not wish to use NRT, among both those who do wish to quit and those who don't. Among those who do wish to quit, smoking reduction using pharmacotherapy and behavioural support appears to be equally effective as abruptly quitting (Lindson-Hawley, Aveyard, & Hughes, 2012).

In a US survey, interest in reduction was highest amongst those who were less interested in quitting and amongst heavier smokers (Shiffman et al., 2007). Also, smokers who do not intend to quit in the next month, but do cut down (with NRT), are more likely to make a quit attempt and be abstinent at follow-up (Wang et al., 2008) than those who do not cut down. Smoking reduction may increase the motivation to quit, which is highly predictive of quit attempts, and reduce smoking dependence, which is related to successful quitting (Vangeli, Stapleton, Smit, Borland, & West, 2011). It has also been reported as part of a practical randomised trial (examining an intervention in an applied setting), that offering an intervention to support smoking reduction may increase the reach of services to smokers who would not engage in cessation programs (Glasgow et al., 2006, 2008). Motivational advice (without NRT) can increase 24-hr quit attempts and 7-day point prevalence abstinence at 6 months (Carpenter, Hughes, Solomon, & Callas, 2004). Behavioural support aims to increase confidence in smokers to cope with cravings and withdrawal symptoms, reduce smoking and ultimately remain abstinent (Hughes & Carpenter, 2005).

There is strong evidence that a single session of physical activity (PA) can support smoking cessation in a variety of ways. A recent meta-analysis of individual participant data from temporarily abstinent smokers (not using pharmaceutical aids) showed a significant reduction in strength of desire and desire to smoke following a brief bout of PA (Haasova et al., 2013). Another meta-analysis examining the effects of PA on withdrawal symptoms and cigarette cravings from 12 included studies also reported positive effects of PA compared with a passive control condition, revealing that the rapid reduction in cigarette cravings, withdrawal symptoms and negative affect associated with a brief bout PA were sustained for up to 50 minutes following PA (Taylor, Ussher, & Faulkner, 2007). A pilot study using a within subject crossover design comparing a passive condition with a ten minute brisk walk resulted in a significant reduction in puff volume and a trend for a shorter puff duration following the active condition (Faulkner, Arbour-Nicitopoulos, & Hsin, 2010). It also reported a significant increase in the time to first puff following the active condition compared to the passive condition. Another experimental study involving 60 temporarily abstinent smokers randomized to either an experimental or control condition also reported a delay in ad libitum smoking following a 15 minute brisk walk, taking nearly an hour longer to smoke their first cigarette compared to a passive condition (Taylor & Katomeri, 2007). This experimental study also showed PA attenuated cue-elicited cravings when presented with a lit cigarette following the experimental condition compared to the passive condition, suggesting PA may be a useful tool in explicitly managing cravings when temporarily abstinent and in supporting reduction through an increased time between cigarettes.

A review of exercise interventions (versus usual care) as an aid for long-term smoking cessation (Ussher, Taylor, & Faulkner, 2014) identified 20 randomised controlled trials (consisting of 5,870 participants). Due to considerable heterogeneity between studies, no meta-analyses were attempted. Most were methodologically limited, with eight involving less than 30 participants in each arm. Of the seven which were adequately powered, four supported significant increases in abstinence at the end of treatment, but only two supported a borderline increase in abstinence rates at 12 month follow up. The populations involved in the studies varied, with nine trials including only women, one trial including only men, one trial including only those who were post-acute myocardial infarction patients, all but four of the studies were North American, only 13 studies reported ethnicity (of which all reported predominantly white samples), and one study included only teenagers. None of the studies included considered outcomes relative to age, occupation or socioeconomic status. Although the review states the interventions were aimed at increasing PA, either alone or as an adjunct to a smoking cessation intervention, compared with a smoking cessation programme alone, they also found great variation in what was being offered and reported. For example, in all but two studies, both arms received a multisession cognitive behavioural smoking cessation programme, in ten studies this was described as being delivered prior to the quit day and in others beyond quit day; one study offered an internet based cessation programme, but this was only available in the control condition; 7 included nicotine replacement therapy (NRT) as part of the cessation programme (which may mask any effects of PA), 3 promoted NRT in general, one promoted smoking cessation medication in general; and 16 studies recruited current smokers who set an explicit quit date with one setting a quit date only for those

in the control condition. The exercise interventions also varied greatly, with 12 studies beginning the exercise programme prior to quit date, three starting on the quit date, three starting after the quit date, and two studies did not state the timing of the exercise programme relative to the quit date. The length of the exercise programmes were also different across studies with two studies involving exercise programmes lasting less than six weeks, and one study provided no details of the exercise programme at all. Most studies employed supervised, group based cardiovascular type exercise supplemented by a home based programme, one used brief one-to-one counselling promoting home based exercise, one focused solely on telephone based PA counselling, one offered a web based support to encourage engagement in a personalised fitness based programme without providing any details, one focused solely on resistance training and one other focused on yoga. Few of the programmes report using exercise and lifestyle modification as a way of explicitly managing cigarette withdrawal and craving. The outcomes reported were also different across studies with varying degrees of rigour: eight studies reported continuous abstinence, two prolonged abstinence, point prevalence abstinence in eight, and two did not specify the measure of abstinence used. Based on the level of heterogeneity in the included in the studies, it is not surprising a meta-analysis was not completed, and through the narrative synthesis presented it is not surprising no formal recommendations are found for promoting PA and exercise for the long term management of smoking cessation, It concludes that the trials that did not show a significant effect of exercise on smoking abstinence were either too small to reliably exclude an effect of the intervention, had numerous methodological limitations, or included an intervention which may not have been intense enough to produce the required changes in exercise levels.

There is also epidemiological evidence to suggest that those who are more physically active are more likely to initiate a quit attempt. A study examining the predictors of smoking relapse amongst smokers completing basic military training in the US Air Force (N=4,303) (Haddock et al., 2000) followed over 1 year revealed that those who made serious quit attempts following basic military training had greater levels of physical activity than those who did not make a quit attempt. This relationship has also been demonstrated in a larger data set of smokers (N=22,659) from the Canadian Community Health Survey (Deruiter, Faulkner, Cairney, & Veldhuizen, 2008) which also found that those smokers who were physically active (n=5,441) were more likely to have made a quit attempt in the past year compared to those who were not physically active (n=17,218). A longitudinal study over a two year period of 1,168 adult smokers in the US reported an association between higher levels of cigarette dependence and lower levels of PA (Loprinzi, Walker, & Cardinal, 2014), however other studies have shown this relationship is influenced by gender (e.g. the inverse relationship between heavy smoking and PA levels is only true amongst men) and mode of PA (e.g. leisure time PA) (Schröder, Elosua, & Marrugat, 2003). A systematic review of empirical relationships between PA and smoking (Kaczynski, Manske, Mannell, & Grewal, 2008) reported that in 60% of 50 studies identified there was a definite negative association between smoking and PA levels, but even this relationship was reported to be attenuated or reversed among adolescents and males for moderate (vs vigorous) PA. Early studies have even reported weak, or no, relationships between PA and smoking (Blair, Jacobs, & Powell, 1985; King et al., 1992).

The mixed nature of the support for PA and its influence on smoking levels and behaviour raises questions over any causal relationships and reveals that it is

likely to be a very complex relationship. Using a well-established criteria for assessing the relationships between two variables as either causal or associative, such as the Bradford-Hill criteria (Hill, 1965) goes some way to uncovering the nature of the evidence for the relationship between smoking and PA. The nine criteria (strength, consistency, specificity, temporality, biological gradient, plausibility, coherence, experiment, and analogy) appear to be met by PA in supporting smoking under different assumptions and types of evidence, which further highlights the complex nature of the relationship between these two behaviours. For example, the association between PA and smoking as revealed through observational, cross sectional and longitudinal studies (although generally the evidence supports a negative association between PA and smoking levels) remains relatively inconclusive, suggesting the criteria for strength of association and consistency are not fulfilled. There is also a lack of evidence to support a dose-response relationship, although some research has made recommendations that a minimum amount of PA is required to impact on smoking behaviour (110 minutes of moderate exercise consisting of 2-3 supervised sessions per week (Marcus et al., 2005) there is no evidence to suggest a cumulative effect. These factors question whether there is plausible causal or associative link between the two behaviours. The criterion of specificity, i.e. the exposure being linked to a single outcome, is difficult to quantify in terms of PA and smoking, as smoking and PA are both behaviors which are strongly clustered with other social and psychological factors, so identifying a specific causal explanation may be difficult which in turn may impact on the strength of association seen between the two behaviours. As reported, the evidence is strongest for PA in the acute reduction of cigarette cravings and withdrawal, and the experimental research investigating this meets

several of the criteria for establishing an association or causality. The criteria has been widely adopted to determine causality but, as has been observed, this should be treated with caution (Höfler, 2005; Ward, 2009), and it has been argued that only the criterion of temporality can truly be considered causal (Rothman, 1998). The strong support for the acute effects of PA on smoking cravings and withdrawal (Haasova et al., 2013) provides support for the criteria of temporality and for the effect holding up under experimental conditions, and it the explicit use of PA to control smoking cravings and withdrawal which may be most pertinent in designing an intervention aimed at using PA to support reductions in smoking behaviour.

Research on the value of PA for smokers wishing to change their smoking behaviour has shown that in general it is viewed as something beneficial and positive. Smokers have reported that they value exercise as a strategy for reducing the risk of developing tobacco-related disease (Haddock, Lando, Klesges, Peterson, & Scarinci, 2004), and that smokers trying to quit are more receptive to an active lifestyle than smokers in general (Doherty, Steptoe, Rink, Kendrick, & Hilton, 1998; King, Marcus, Pinto, Emmons, & Abrams, 1996). This suggests that the possibility of introducing PA at a time when somebody is trying to quit maybe feasible and well received, but as highlighted from previous reviews the best way to promote PA is unknown.

The support for PA in being beneficial for smoking behavior across different types of evidence suggests there is scope to explore if PA could facilitate smoking reduction and cessation induction among those not wishing to quit immediately. The existing body of research has not focused on disadvantaged

smokers and there is scope for research within this group to determine how best to increase PA and decrease smoking prevalence.

Disadvantaged and low socioeconomic status groups are less likely to meet the recommended daily guidelines for physical activity in the UK (Roberts, Cavill, Hancock, & Rutter, 2013). Among disadvantaged groups in general the relationship between PA and socio-economic status among adults is type dependent, i.e. leisure time physical activity compared necessary PA such as that related to occupation or active transport. Disadvantaged groups undertake less leisure-time PA but undertake more activity associated with work and active transport (in part due to low car ownership) (Cerin, Leslie, & Owen, 2009; Cerin & Leslie, 2008; Turrell, Haynes, Wilson, & Giles-Corti, 2013). This relationship clouds an understanding of the effectiveness of interventions to generally increase PA (Cleland, Tully, Kee, & Cupples, 2012). But importantly, a systematic review including 27 studies of interventions to increase PA in socioeconomically disadvantaged groups showed those interventions which were underpinned by any theoretical framework, compared to none, were more likely to be effective, albeit among a small number of studies with adults (Cleland et al., 2012). Whilst the review reports interventions which were based on a behavior change theory were more effective than those which were not, the poor descriptive details provided by the authors of the individual studies prevented any meaningful mapping of intervention components on to the described theories suggesting the effective components of such interventions are yet to be fully investigated and described.

There are several ways in which an increase in PA may putatively facilitate smoking reduction and cessation induction (Taylor & Ussher, 2013). In addition

to smokers explicitly using short bouts of PA to cope with cravings and withdrawal symptoms (see above) it may also help to reduce the substantial weight gain associated with cessation (Aubin, Farley, Lycett, Lahmek, & Aveyard, 2012). On average, smokers experience almost 5 kg of weight gain, with 13% gaining over 10kg, in the first year after quitting (Aubin, Farley, et al., 2012). In a limited number of studies, increasing PA has been shown to be a useful strategy to prevent weight gain among those quitting smoking (Farley, Hajek, Lycett, & Aveyard, 2012), and is popular with smoking cessation practitioners (Everson, Taylor, Ussher, & Faulkner, 2010). PA may be effective by both increasing energy expenditure and enhancing self-regulation of emotional snacking associated with low mood (Blundell & King, 2000; Oh & Taylor, 2013). Of relevance to the present study, systematic reviews and prospective cohort studies suggest that people of lower socio-economic status, and heavier smokers (among other characteristics) are at increased risk of weight gain (Lycett, Munafo, Johnstone, Murphy, & Aveyard, 2011).

Smoking prevalence is greater among people with mental health problems, perhaps because nicotine may improve concentration and cognition, relief of stress and depressive affect, and increase pleasurable sensations (Aubin, Rollema, Svensson, & Winterer, 2012). PA, defined as “planned, structured and repetitive bodily movement done to improve or maintain one or more components of physical fitness”, can reduce depression (Rimer et al., 2012). This is supported by a variety of evidence including observational studies where higher levels of PA are associated with lower levels of depression (Biddle, 2000; Goodwin, 2003). Whilst an association does not imply causation, there are several reasons why PA may improve mood, including PA as a diversionary activity from negative thoughts and the mastery of a new skill (Lepore, 1997),

having an anti-depressive effect through increasing self-efficacy which is intricately linked to self-esteem (Craft, 2005), which is considered to be one of the strongest predictors of subjective well-being (Diener, 1984), and through a variety of physiological mechanisms such as changes in endorphin and monoamine levels or a change in the levels of the stress hormone cortisol (Duclos, Gouarne, & Bonnemaïson, 2003), and possibly through stimulating the growth of new nerve cells and the release of proteins known to improve health and survival of nerve cells (Cotman & Berchtold, 2002; Ernst, Olson, Pinel, Lam, & Christie, 2006). PA has also been reported to help reduce anxiety (Taylor, 2000) and as such may speculatively may replace the need to smoke.

In laboratory studies, a single session of exercise appears to reduce attentional bias to smoking cues (Van Rensburg, Taylor, & Hodgson, 2009), and reduce activation in areas of the brain associated with reward seeking while viewing smoking-related images (Janse Van Rensburg, Taylor, Benattayallah, & Hodgson, 2012). Finally, it may be reasonable to speculate that undertaking more PA may help or reinforce a shift from the identity of a smoker to that of an exerciser, with the potential for a reduced exposure to environments and cues associated with smoking. In a cross-sectional survey the negative association between PA and smoking was mediated by having a physically active identity (Verkooijen, Nielsen, & Kremers, 2008). Thus by simply increasing PA there may be implicit positive effects on smoking habits.

At least fifty cross-sectional surveys have assessed the association between self-reported PA and smoking status (Kaczynski et al., 2008), with most reporting a negative association. Physically active smokers are more likely to have attempted cessation in the past year than inactive smokers (Deruiter et al.,

2008). However, randomised controlled trials to assess the effects of a primary care intervention to promote PA have shown that increases in PA were not associated with concurrent reductions in smoking among the sub-sample of smokers in the study (Bull & Jamrozik, 1998; Taylor, Doust, & Webborn, 1998). Whilst these studies were not powered to detect these effects, this evidence questions the idea that simply increasing PA will lead to a spontaneous change in smoking behaviour.

The challenge then is to design a PA promotion intervention that explicitly helps a smoker to build a connection between doing PA and smoking reduction.

Within the UK, such an integrated intervention was piloted among smokers who were attempting to quit with the help of smoking cessation practitioners (Taylor, Everson-Hock, & Ussher, 2010). There are mixed views on whether multiple behaviour changes (e.g., increases in PA and dietary change) should be tackled simultaneously or sequentially when smokers quit (McEwen et al., 2006).

Anecdotal evidence suggests that attempting to modify diet and PA while quitting is not detrimental to successfully quitting and can be facilitative (Everson-Hock, Taylor, & Ussher, 2010; Koshy, Mackenzie, Leslie, Lean, & Hankey, 2012). However, an integrative approach has not been developed or evaluated for disadvantaged smokers who do not wish to quit abruptly but do want to reduce smoking.

1.2 The Exercise Assisted Reduction then Stop smoking (EARS) Study – Summary

The key objectives of the Exercise Assisted Reduction then Stop Smoking (EARS) study were:

1. To develop a multi-component PA intervention aimed at helping smokers (not intending to quit in the next month) to cut down then quit, in conjunction with professionals working with disadvantaged groups.
2. To qualitatively assess the acceptability of such a PA intervention as an aid to cutting down, among disadvantaged smokers.
3. To qualitatively assess the acceptability of recruitment, assessment and randomisation procedures within a pilot pragmatic randomised controlled trial to compare the effects of a PA intervention versus brief advice (usual care) on quitting, among disadvantaged smokers.
4. To obtain an estimate of the intervention (PA v brief advice) effect size and its precision to inform sample size calculations for a fully powered trial, from a pilot randomised trial to assess expired air carbon monoxide (CO) confirmed abstinence at 4 weeks post-quit date.
5. To assess process measures at 4, 8 and 16 weeks post-baseline including: self-reported cigarettes smoked; number of quit attempts; self-reported quality of life; mood & physical symptoms; cravings; PA by self-report and accelerometer (in a sub-sample); pharmacological and behavioural support used; and weight.
6. To estimate the resource use and costs associated with delivery of the intervention, and to pilot methods for determining future cost-effectiveness analyses.

1.3 Methods

We carried out an individually randomised, single centred pilot RCT comparing an integrated smoking reduction and PA promotion intervention in addition to usual care against usual care (which at the time of writing was to provide information about quitting). The randomisation rate was 1:1 and completed via a web based randomisation sequence and minimised by HT (one of three), age (over/under 30 years), smoking dependence (high/low), and gender.

Participants were recruited through three approaches:

1. Mailed invitation (with telephone reminders) via three GP surgeries in the targeted communities.
2. Mailed invitation (with telephone reminders) via the local SSS to residents of the targeted communities.
3. A wide range of other community based approaches (e.g. media exposure, networking, attending local community centre events).

Participants were eligible to enter the study if they: were over 18 years old, smoked at least ten cigarettes per day (and had done so for at least two years), did not want to quit in the next month, were able to engage in moderate intensity PA (walk without stopping for at least 15 minutes, a measure introduced as part of the screening process which was considered easily applicable within a pragmatic setting and would capture those who are capable of engaging in moderate PA or higher (Kelly, Murphy, Oja, Murtagh, & Foster, 2011)), were registered with a GP, and did not wish to use nicotine replacement therapy (NRT) to reduce smoking. The study focus was on initially reducing smoking, not quitting, so those who expressed an immediate desire to quit were referred directly to the SSS without entering the study. Those wishing to use NRT were excluded to avoid any confounding of the effects of PA on their

smoking behaviour. We excluded those with severe mental health problems and on-going substance misuse who may have put the safety of the research team at risk. Given the exploratory nature of the study participants were required to be able to converse in English.

The primary outcome was expired air CO confirmed abstinence 4-8 weeks after quitting, among those who made a quit attempt whilst involved in the study. Secondary outcomes included those reducing their smoking by at least 50% from baseline, self-reported and objectively measured PA levels, along with several other behavioural, emotional and cognitive variables, at 4, 8 and 16 weeks.

Extensive data on recruitment activity, time invested, response rates, and randomisations rates were recorded for all recruitment approaches for comparison.

Comprehensive qualitative work was completed in order to address issues of acceptability and feasibility about the trial and intervention design and methods. This included the following: interviews with the HTs early and late in the trial; fidelity coding of a selection of recorded (and transcribed) intervention sessions against an 11 item fidelity coding framework based on the expected active components of the intervention; the identification of examples of good practice for future training from, interviews with 25 completing participants to assess acceptability of the intervention and trial methods and further identification of the perceived effective intervention components.

Data were collected within-trial, via work sampling procedures, and trial level data collection, to inform estimates of the resource use and associated cost for the EARS intervention. Longer term outcomes associated with estimates of the effectiveness of the EARS intervention, and the cost effectiveness of the intervention compared to brief advice were explored.

The PA intervention was client-centred and counselling based, with sessions taking part face-to-face in a local multi-use NHS building (or by phone) over eight weeks, with up to a possible further six weeks support following a quit attempt. A written EARS intervention manual was provided for the HTs, designed to build on existing HT competencies.

1.4 Results

A total of 99 participants were randomised from the three recruitment approaches with a 62% follow up rate at 16 weeks. Sixty-two were recruited through mailed GP practice invitations (plus varying intensity of reminder phone calls) and 31 through mailed SSS invitation (with varying intensity of reminder phone calls). Depending on the intensity and time invested in following up those who did not initially respond to the letters, we randomised between 5.1% - 11.1% of those invited, with associated researcher time to recruit one participant varying from 18 to 157 minutes. Despite substantial time and effort, only six participants were recruited through other community based approaches, with an associated researcher time of 469 minutes to recruit one participant. Participant demographics did not differ as a result of recruitment location or approach. Recruitment targets for a pre-defined disadvantaged population were met, with 91% of the sample in social class C2-E, up to 41%

demonstrating mental health problems, and a small sample of single parents being recruited.

At baseline 49 were randomised to the intervention arm, and 50 to the usual care arm. Adherence to the intervention was generally positive, with 88% attending at least one intervention session and 59% attending at least four sessions. The mean number attended was four.

In the intervention and control arms, respectively, 22% vs 6% (relative risk (RR) (95% confidence interval (CI)) = 3.74 (1.11;12.60)) made a quit attempt, 14% vs 4% (3.57 (0.78;16.35)) had expired air CO confirmed abstinence 4-8 weeks post quit, and at 16 weeks 10% vs 4% (2.55 (0.52;12.53)) achieved point prevalence abstinence, and 39% vs 20% (1.94 (1.01;3.74)) achieved at least a 50% reduction in the number of cigarettes smoked daily. As the study was not powered for hypothesis testing, no inferred statistical significance of these results were reported.

Qualitative data from both recorded sessions and participant interviews showed that the HTs generally delivered the planned intervention as intended and that it was largely acceptable among interviewed participants. However, the intervention fidelity analysis identified several areas for improvement (e.g. in exploring social influences and those linked with PA) with associated implications for updating the training course. Interviews with patients and the HTs identified further possible adaptations and refinements for future practice, and effective components of the intervention (e.g. the process of engagement, behavioural strategies for smoking reduction, and to a lesser extent the promotion of PA). Issues surrounding the complexities of integrating PA and smoking reduction were highlighted and will inform refinements to the process

model of how people use PA to manage smoking behaviour (and the related intervention processes).

The cost effectiveness analysis estimated the mean cost of the EARS intervention at £192 per participant. It also provided valuable information on how to assess the cost effectiveness of a future phase 3 definitive RCT, indicating the required scope of any modelling in the context of the EARS intervention. Exploratory cost-effectiveness analyses suggested that the EARS intervention is likely to be cost effective where it is confirmed to be low cost and where the intervention effectiveness could be demonstrated.

1.5 Conclusions

1.5.1 Implications for future research

A larger, fully powered trial is needed to confirm the effectiveness and cost-effectiveness of the EARS intervention. Minor refinements to the intervention may increase acceptability and effectiveness. Further exploratory work is needed (e.g. four months) on adapting the intervention for a more ethnically diverse sample. A larger study would add further information about the core effective components of the intervention, and any moderators and mediators of any effects. A follow-up of at least six months post-intervention is needed to provide evidence of long-term effectiveness.

1.5.2 Implications for health care

It is premature for any guidance for health professionals, policy makers, and commissioners to be derived from the present study. The findings provide preliminary support for the EARS intervention but a larger study is required to provide more confidence in the findings in a wider range of participants and settings. The study is timely in light of the recent NICE guidelines on harm

reduction for smoking which calls for further research on the effects of behavioural support for smoking reduction and cessation induction.

1.6 My contribution to the main research and thesis content beyond the EARS study

1.6.1 Key contributions to the EARS study:

1. Prepared NHS ethics submission for the EARS pilot trial.
2. Designed, prepared, collated and transferred all measures (for data collection) onto Teleform scanning software. Including piloting the scanning procedures and developing excel databases at each assessment time point. Finally I led the scanning and checking of all data for the pilot trial.
3. Co-prepared the EARS Health Trainer training manual and related training materials.
4. Collected field notes on HT training and working with test smokers. This resulted in a poster presentation drawing on 6 case studies.
5. Co-established the remote research office (NHS Cumberland Centre, Devonport, Plymouth) with 3 appointed part time HTs/researchers.
6. As trial manager I had a number of responsibilities including:
 - The overall efficient day-to-day management and operationalisation of the trial.
 - Recruitment, retention, training, appraisal and supervision of trial team members.
 - Establishment of procedures to ensure adherence to trial protocols and administrative requirements.

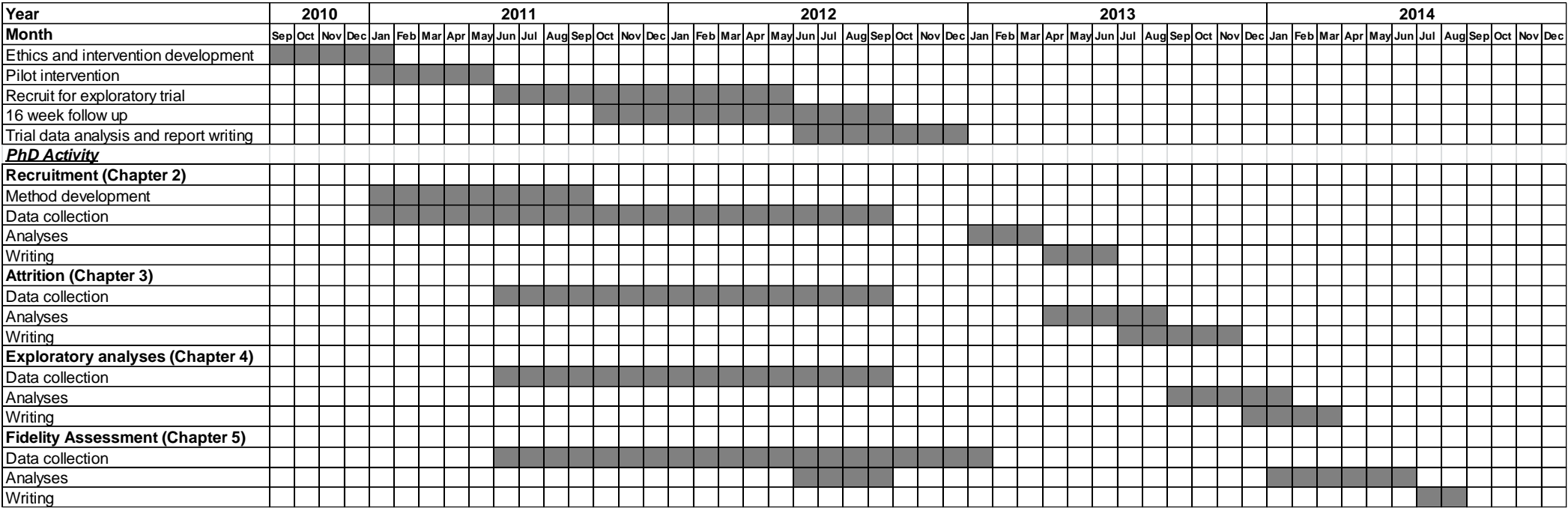
- Ensuring the timely recruitment of trial participants with secure randomisation processes and subsequent efficient and effective data management.
- Monitoring the trial progress to ensure compliance with and adherence to the project plan and to identify, evaluate and rectify problems.
- Acting as the point of contact for all external and internal agencies.
- Coordinating the preparation and publication of data, reports and information, ensuring that these meet legislative, contractual and ethical requirements.
- Understanding the requirements of the various controlling bodies, agencies and frameworks, guiding the project in conforming to those requirements and coordinating any necessary audit processes.
- Liaising with the Trial's Steering Committee with a particular view on compliance with Research Governance, Good Clinical Practice, Data Protection and Ethical Requirements.
- Provision of regular and ad hoc information, both written and verbal, to all the trial participants and sponsors, including reports, updates, and guidance.
- Working with the Principal Investigator to ensure that the trial was meeting its targets, producing meaningful output and to predict and plan any changes that warrant requests to changes in protocol, funding or time.
- Planning and supporting the meetings and work of the various groups and bodies associated with the trial.

- Creating and maintaining all trial files, including the trial master file, and overseeing site files.
 - Assuring that personal and confidential information was restricted to those entitled to know.
7. Substantial contribution to the writing of the HTA final report and preparation for submission.

1.6.2 Thesis content beyond the EARS study

This thesis presents new research building upon the work completed within the EARS study. The candidate led on the design, implementation, and writing up of all subsequent work. Chapter 2 presents detailed analyses of recruitment activity and its results in accessing a disadvantaged population of smokers. Chapter 3 presents analyses of study attrition with an exploration of several factors of interest relating to potential causes of drop out. Chapter 4 builds upon the main findings and explores further the outcomes related to smoking and PA with exploratory analyses relating to missingness and intention to treat analyses. Chapter 5 builds upon the intervention delivery fidelity and examines the weaknesses and strengths of the approaches taken in the main trial. A GANTT chart covering the main EARS trial and summarizing the work of the this thesis as it occurred alongside and after the EARS trial is shown in *Figure 1*.

Figure 1 EARS main trial and PhD Gantt chart



2. LESSONS LEARNED FROM RECRUITING SOCIOECONOMICALLY DISADVANTAGED SMOKERS INTO A PILOT RANDOMISED CONTROLLED TRIAL TO EXPLORE THE ROLE OF EXERCISE ASSISTED REDUCTION THEN STOP (EARS) SMOKING

A version of this chapter has been published in *BMC Trials* (Thompson et al., 2015).

2.1. Background

Smokers from disadvantaged groups (e.g., unemployed, low-skilled manual workers, people with mental health problems) attempt to quit at the same rate as others but their success in quitting is lower (Hiscock, Bauld, Amos, Fidler, et al., 2012). Smoking has been identified as one of the main contributing factors to health inequalities in industrial countries (Chandola, Head, & Bartley, 2004) and in England and Wales accounts for nearly half the difference of smoking-attributed mortality (among males) between the highest and lowest socioeconomic groups (Jha et al., 2006). Smoking reduction may increase the motivation to quit, which is highly predictive of quit attempts, and reduce smoking dependence, which is related to successful quitting (Vangeli et al., 2011). Also, offering an intervention to support smoking reduction may increase the reach of services to disadvantaged smokers who would not engage in cessation programmes (Glasgow et al., 2006, 2008). Offering support for smoking reduction may attenuate the commonly reported barriers to engagement of 'fear of failure' and 'fear of being judged' when attempting to abruptly quit (Murray et al., 2009).

Evidence for the effectiveness of smoking cessation interventions for disadvantaged groups is limited (Bryant et al., 2011; Hiscock, Bauld, Amos,

Fidler, et al., 2012; Michie, Jochelson, Markham, & Bridle, 2009; Ranney et al., 2006). The lack of evidence may have resulted from both the inherent difficulties in recruiting and engaging with such groups in clinical trials, and the predominant focus on abrupt quitting rather than smoking reduction. Further research is therefore needed on how best to recruit disadvantaged smokers to increase intervention reach with appropriate behavioural support (Michie, Jochelson, et al., 2009; Michie, Rumsey, et al., 2008; Murray et al., 2009).

More detailed and transparent information on the reach of trials and interventions (e.g., the proportion of the targeted population that participated) targeting disadvantaged groups is needed to better assess and plan interventions (Glasgow, Vogt, & Boles, 1999). Various approaches may improve recruitment into studies among disadvantaged groups (Flanagan & Hancock, 2010; Sixsmith, Boneham, & Goldring, 2003), including the following: engagement with the target population when developing the intervention and preparing participant information about the study and intervention; using a variety of community networks and settings to invite the target population; and use of follow-up telephone calls to explain the study methods and intervention. In a review, the most effective strategies for recruiting smokers into trials (Marcano Belisario, Bruggeling, Gunn, Brusamento, & Car, 2012) suggested that tailored interventions, recruitment methods that are proactive in nature (e.g. approaching potential participants directly) (Collins et al., 2011), and more intensive recruitment strategies (e.g. repeated provision of information and contact) as opposed to passive recruitment methods (e.g. local advertisements), may help. But in general there is insufficient knowledge regarding the factors influencing recruitment and most effective strategies for recruiting into randomised trials (McCann, Campbell, & Entwistle, 2013;

McDonald et al., 2006; Treweek et al., 2013), particularly among disadvantaged groups. Most research examining recruitment approaches has focused on drug or medical interventions rather than public health interventions (Toerien et al., 2009), and trials on physical activity are often criticised for their failure to recruit a broad population and further research is needed on the best ways to recruit a more diverse population into PA research (Ogilvie et al., 2007).

It has been highlighted that although existing frameworks for guiding the design, implementation, and reporting of research trials (such as the RE-AIM framework (Glasgow et al., 1999) and CONSORT guidelines (Murphy, 2010)), which highlight recruitment as part of their framework, the guidelines do not provide guidance on the actions needed to identify and recruit potential populations of participants (Foster et al., 2011). Foster and colleagues (2011), as part of a systematic review of recruiting participants to walking interventions, highlight a criteria for assessing study quality in relation to recruitment in order to promote a better understanding of recruitment methods and their relative success and resource use, including: (i) did the study report where the population was recruited?, (ii) did the study report who conducted the recruitment?, (iii) did the study report the time spent planning/preparing the recruitment?, (iv) did the study report the time spent conducting the recruitment?, and (v) did the study target a specific population? This chapter attempts to present the data related to recruitment in such detail that these criteria are met. Foster and colleagues (2011) suggest that the “pool” of all possible participants should be reported in order to give a more truthful metric in relation to the reach and efficiency in recruiting a specific population (as well as to inform overall cost-benefit calculations) however this was not possible within the current research as

ethical permission was not obtained to profile those not identified through initial screening activities within GP practice databases.

This article reports on the feasibility and acceptability of strategies specifically designed to recruit disadvantaged smokers who wished to reduce their smoking but not quit, into a phase 2 pragmatic pilot randomised controlled trial: the Exercise Assisted Reduction the Stop (EARS) trial (HTA no. 07/78/02, ISRCTN 13837944, UKCRN Study ID 8937). The specific objectives of this study as related to the present paper were: (i) to identify the feasibility of recruiting disadvantaged smokers through a variety of settings (i.e. through primary care, National Health Service (NHS) Stop Smoking Services (SSS), and through more generalised community approaches). Additionally to examine the effect of using varying degrees of recruitment activity intensity (i.e. recruitment by invitation letter only compared with an invitation letter plus follow-up reminder telephone calls, and through various levels of community engagement); (ii) to examine how recruitment of participants through different locations and different levels of recruitment intensity impact on participant characteristics; (iii) to identify the time requirements associated with each recruitment approach; and (iv) to qualitatively explore the effectiveness and acceptability of different approaches to recruitment.

Overall, the trial sought to identify uncertainties about the methods and intervention to support smoking reduction with physical activity and behavioural support. The two arm randomised controlled trial consisted of a weekly one-to-one counselling based intervention of up to 12 weeks supporting self-directed changes in smoking and physical activity behaviours, compared with usual care, among disadvantaged smokers wishing to cut down but not quit. Data collection

took place at baseline, 8 weeks, and 16 weeks post baseline. The primary outcome was the number of participants achieving 4 weeks post quit expired air carbon monoxide confirmed abstinence. Other outcomes included the number of quit attempts made, the number achieving at least 50% reduction in smoking at 16 weeks, changes in physical activity, and various other behavioural and process measures. The protocol and main findings of the study have been published (Taylor et al., 2014).

2.2. Methods

2.2.1 Locating and defining a disadvantaged population

We set a target to recruit participants of whom at least 75% were unemployed or in social class C2–E (skilled manual workers, semi-skilled and unskilled manual workers, state pensioners, casual and lowest grade workers, and those unemployed with state benefits only), 30% were single parents, and 20% had indicators of a mental health problem (indicated by answering ‘moderately’ or ‘extremely’ anxious or depressed to item 5 of the EQ-5D questionnaire). These criteria were based on the high prevalence of smoking among these groups (Hiscock, Bauld, Amos, Fidler, et al., 2012). Recruitment took place in the neighbourhoods of Devonport and Stonehouse in Plymouth, UK, selected for having high deprivation (index of multiple deprivation score 52–59.9, placing them within the 3% ‘most deprived’ in England (Department of Communities and Local Government, 2011). Local data indicated that smoking prevalence among adults was >40%, and the location had generally poor health with life expectancy 12.6 years lower than some other areas of the city (Public Health Plymouth, 2013).

2.2.2 Inclusion/exclusion criteria

Participants were eligible if they were over 18 years old, smoked at least 10 cigarettes per day (and had done so for at least 2 years), did not intend to quit in the next month, were able to engage in moderate intensity physical activity (walk without stopping for at least 15 minutes), were registered with a general practitioner (GP), and did not wish to use nicotine replacement therapy (NRT) to reduce smoking. The study focus was initially on reducing smoking, not quitting, so those who expressed a desire to quit immediately were referred directly to the NHS SSS without entering the study. Those wishing to use NRT were excluded to avoid any confounding of the effects of physical activity on their smoking behaviour. We excluded those with severe mental health problems and ongoing substance misuse, due the potential difficulties of engaging them in the intervention given the large uncertainties and complexities of its delivery, and those who may have put the safety of the research team at risk. Due to the exploratory nature of the study, participants were required to be able to converse in English. No threshold was placed on baseline physical activity levels for two reasons: 1) as part of the exploratory nature of the trial the baseline PA levels of those recruited was of interest, 2) the theoretical basis for the intervention in promoting PA to support smoking reduction meant that the type and timing of PA to explicitly control smoking related cravings and withdrawal meant that overall PA levels may not be crucially important.

2.2.3 Recruitment

Recruitment was over a 12-month period between May 2011 and May 2012, with a recruitment target of 120 smokers. Recruitment was split between two distinct approaches: (1) primary care, and (2) other community-based approaches, in order to explore the efficacy of recruiting through existing health services and those engaged with it and to explore more alternative community

based approaches to see if a different population could be recruited to increase the reach of recruitment to those who may be considered more service resistant.

Primary care

Initially, one primary care medical practice in each of the two neighbourhoods was identified and approached to be included in the research study; a third practice with patients from both areas was approached later in the study in order to expand the scope of recruitment to meet the planned sample size. We planned to recruit 50% (n=60) of participants through primary care. GP Practice lists were searched based on cursory inclusion/exclusion criteria (see Taylor et al, 2014, for more details). A list of potential participants was generated and invitation letters, in batches of 100 per practice, were sent every 2 weeks from the GP with a postal reminder a week later. To begin with, postal invitations were sent without making any follow-up telephone calls so a response rate to a letter only invitation could be established. Following on from this, and to increase reach to people with low literacy, telephone calls were made to those who did not respond directly to the invitation letter to check that they had received and understood the invitation, and to explore the effect of follow-up calls on increasing recruitment rates. If there was no answer on the first call a message was left to enquire if the invitation had been received and to leave a contact number for further information. Up to four more calls were made but, to avoid harassment, no further messages were left. Interested participants returned a form indicating interest in the study or telephoned a researcher. They were then screened for eligibility by telephone, and provided consent for a researcher to contact their GP to confirm eligibility; once eligibility was

confirmed by their GP, the volunteer was invited to attend a baseline assessment.

Community

The other 50% (n=60) of the targeted recruitment was categorised as 'other community approaches'. There were two distinct recruitment methods. The first (for which a target of n=30 was set) involved the searching of the local NHS SSS database for people who had used the service within the last 2 years but had failed to quit. The same procedure of mailed invitations and follow-up telephone calls as used for recruitment through GP practices was then adopted, without applying the cursory inclusion/exclusion criteria in the first instance. The second method involved outreach in an attempt to recruit smokers who may not engage with traditional services and may experience higher levels of disadvantage. Potential participants were contacted through: workplaces, educational sites community sites, and a range of other media (see *Table 1*). Interested participants contacted the research team directly (in person) and indirectly by telephone or by returning contact details with a request for further information. Following screening, to determine eligibility, a time for attending a baseline session was arranged.

Informed consent was obtained from all successfully recruited participants before being randomised into the trial.

Table 1 Locations and activities involved in community recruitment

WORKPLACE SITE	Recruitment activity
Local adult education and training provider	Flyers and information packs in the reception. Contact at centre informed about study and given packs to distribute.
Post Office MDEC (Manual Data Entry Centre)	Information cascaded through managers to all employees in team briefings.
EDUCATIONAL SITE	
Local Primary School	Article in parent newsletter with study contact details.
Parent/Toddler groups;	Mother/toddler groups visited through Sure Start. Researchers attended groups and talked with parents. Posters and packs

Several local children's centres;	left, or given out during groups. Collected details of interested persons.
COMMUNITY SITE/ORGANISATION	
Job Centre (Devonport)	Researcher outside Job Centre approached smokers explaining the study; 100 packs and reply sheets given out over several periods in a week. Contact details of interested persons collected.
Local community hub cafe	Local health promotion sessions and food bank sessions attended by researchers; information given out to interested persons.
Local community Cooperative organisation	Flyers and posters given out to a local community employer for distribution.
YMCA (Community run gym)	Posters on display. Fitness Manager promoted study to users of the Stonehouse Gym. Researchers attended a children's session; one pack given out.
Local Gym	Gym instructors informed about study and provided with information packs and reply sheets to distribute to interested persons.
Local Social Club	Central contact informed about study and provided with information packs and reply sheets.
Public Health	Posters and information packs with reply sheets given to the local health club in Devonport.
3 Local Housing Associations	180 flyers distributed through mailboxes in housing association residences in Plymouth; Flyers distributed and attendance at residents' meetings. Posters, flyers and packs left at site for visitors.
Neighbourhood Managers (City Council)	Researchers met with managers in Devonport & Stonehouse. Information distributed.
Local Community Learning Centre	Information and flyers displayed. Researchers attended information sessions. Contact details of interested persons collected.
OTHER	
Local Library	Flyers and posters on display.
Heart Radio/Plymouth Sound/Radio; local paper	Radio chat about the study and news advert in paper.
Word-of-mouth	First 60 trial participants asked to invite friends/ acquaintances to join study once they had completed final follow-up.
Individual contacts (e.g. church minister, day support facility member, publican)	Posters displayed by contacts.
Increasing Access to Psychological Therapies Service, Plymouth	Met and encouraged Psychological Well-being Practitioners to refer to the study opportunistically. Left flyers, information packs and reply sheets to be distributed. Encouraged by e-mail.
Posters displayed around local shops and businesses	Trial posters with contact details displayed in up to 50 local shops and businesses, (e.g., newsagents, hairdressers, tattoo parlours etc.).

2.2.4 Data collection

Data collection consisted of four elements:

- (i) Numbers of: invitation letters sent, responses received, telephone calls made, participants declining participation, participants who were

ineligible, and participants entering the trial through which recruitment location were all recorded on databases throughout the recruitment period at the recruitment location and individual level to allow conversion rates to be produced by recruitment location and by recruitment activity intensity.

- (ii) As part of the main trial, the following data was collected at baseline: demographic information (i.e. age, sex, cohabiting status, cohabiting with other smokers, whether they were the parent of a resident child under 16, job status, age at leaving full time education, ethnicity, weight, and height), smoking history (age on starting smoking, longest period of cessation in last year, attempts at cutting down, cessation aids used in past year, use of SSS, satisfaction with previous use of SSS), number of cigarettes being smoked per day, Fagerström Test for Nicotine Dependence (FTND) (Fagerstrom, 2012; Heatherton, Kozlowski, Frecker, & Fagerstrom, 1991) scores, stage of readiness to use physical activity to control smoking behaviour (scored as either pre-contemplation, contemplation, preparation, action, or maintenance), expired air carbon monoxide (CO) with cessation/abstinence defined as less than 10 parts per million (PPM) (Bedfont Smokerlyser, UK), and physical activity data (self-reported 7 day recall of physical activity and by accelerometer (Actigraph GT3X, Pensacola, USA)). In the present paper this data was used to compare the characteristics of those recruited through different locations and via different recruitment activity intensity.

- (iii) The time spent by the research team on recruitment activity including: searching GP and SSS databases for potential participants (including screening potential participants for eligibility for GP databases only), on the preparation and mailing of invitation letters, making follow up phone calls to non-responders to the mailed invitation, contacting interested participants to screen for eligibility, and arranging baseline appointments were recorded on the trial database. Additional information relating to the time spent recruiting through broader community approaches was recorded via researcher activity logs, diaries, and work sampling procedures.
- (iv) Qualitative data were collected through a combination of field notes, regular documented meetings, audio recorded interviews with the research team, and opportunistic feedback from stakeholders. Semi structured, audio recorded interviews were also completed with the use of topic guide on a purposively sampled range of participants after completing the trial to cover a range of demographics and achieved outcomes.

2.2.5 Data analyses

To calculate the conversion rates from invitation to entry into the trial, a percentage was derived from the total number of invites sent out via each location and the resulting number of randomisations from each location. Conversion rates for broader community approaches was not possible to determine due to the open ended nature of the majority of the methods (it is unknown how many people may have read a flyer/ poster etc. and therefore impossible to derive a denominator).

Pearson chi squared and t-tests were completed for categorical and continuous variables respectively to compare characteristics of those recruited through primary care and SSS, and to compare those recruited by initial invitation letter only or by initial invitation letter plus follow up telephone calls. Statistical analyses were completed using Stata SE (v.12.0).

To calculate time associated with various recruitment methods, the time associated with samples of invitations sent to groups of potential participants sent via each location which received the same intensity of effort (considered to represent best practice) was totalled and divided by the number of participants successfully recruited. All time associated with broader community approaches was also totalled and divided by the number of participants successfully recruited via these approaches. This resulted in a total amount of time spent by the research team per participant randomised. Reasons for ineligibility were also recorded. All trial participants had consented at baseline to being approached by an independent qualitative researcher (TT), to capture their experiences associated with the study and the intervention for those in this arm of the study via a telephone interview.

During the delivery of the intervention the research team regularly discussed the progress of individual participant progress and the nature of engagement with the intervention. We were particularly keen to identify intervention participants who appeared to have benefitted from the intervention and be examples of good practice, possibly for future use in training. As many participants as possible who engaged with the intervention were interviewed by TT.

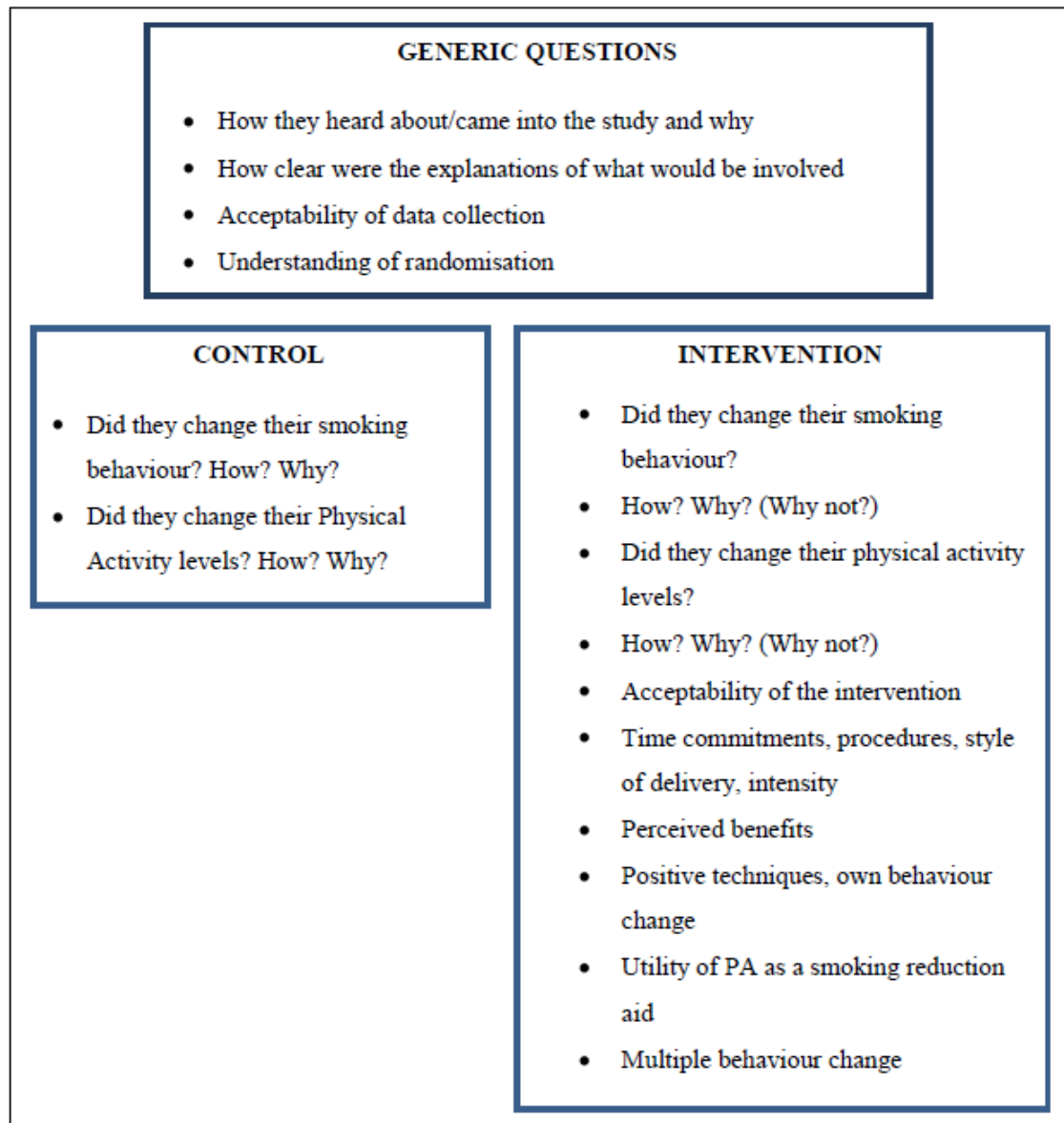
Control participants were selected at random. Participants sampled were contacted by telephone and a convenient time to conduct the interview by

phone was arranged. No participants contacted declined to be interviewed. Verbal consent was obtained for the interviewed to be digitally recorded. All interviews were digitally recorded and transcribed verbatim for further analysis.

Participants were interviewed within 16 weeks of completing the study. The interviews followed the guide shown in *Figure 2* for controls and intervention participants, respectively.

Qualitative research was conducted using a basic thematic analysis of individual telephone interviews to elicit and describe the participants' experiences and views about their experience of engaging with the trial.

Figure 2 Topic guide for interviewing completing participants



An opportunity sample consisting of all three part-time HTs (with a dual role of also collecting data) employed in the study was used to maximise the diversity of opinions in the data. Interviews were conducted both early in the study (1-2 months after starting to deliver the intervention in the pilot trial, to capture experiences of the training course while they were still fresh in the HTs' memories) and in the last 1-2 months of the 16 month pilot trial (to capture any changes in practice or opinion following extended experience of delivering the intervention).

Semi-structured, individual, face-to-face interviews were conducted within a few months of completing the training and at the end of the intervention period) using topic guides developed by AT, CGVS and TT. The first interview started with general questions about the HTs' experiences of delivering the intervention and then asked specific questions about the training course, recruitment processes, intervention delivery (what was working well or badly) and the HT's understanding of the different intervention processes. The second interview (at the end of the intervention phase) asked about their ongoing experiences in delivering the intervention and how these might have changed since the initial interview. The interviews were digitally recorded and transcribed verbatim.

The data were organised using a basic thematic analysis to provide a simple descriptive-level overview of the HTs' views. In-depth qualitative analysis procedures were not used here.

Interview transcripts were analysed using the qualitative software package NVivo (Version 9.2). The data were organised using a basic thematic analysis to provide a simple descriptive-level overview of the participants' views and experiences. Ethical approval for the study was granted by the NHS National Research Ethics Service Committee South West, in the UK (LREC no.: 10/H0106/59) (see *Appendix 1*).

2.3. Results

2.3.1 Recruitment rates

Invitations sent from primary care (with no follow-up telephone calls, n=361) led to 5.1% of those invited being randomised into the study. With attempted contact by follow-up telephone calls to non-responders (n=485) this proportion increased to 8.8%.

Invitations sent from SSS (with no follow-up telephone calls, n=255) led to 6.8% of those invited being randomised into the study. With follow-up telephone calls to non-responders (n=137) this proportion increased to 11.1%.

2.3.2 Comparison of participant characteristics

Baseline descriptive data for the recruited sample can be found in *Table 2*.

Those recruited through SSS, compared with primary care (PC), were more likely to be recruited through letter invitation ($X^2(1, N=93) = 6.43, p = 0.01$), to have used cessation aids before ($X^2(1, N=93) = 26.35, p < 0.01$), and to have made a quit attempt in the past year ($X^2(1, N=93) = 8.23, p < 0.01$). No other variables were associated with recruitment from primary care or SSS in univariate analyses.

Table 2 Sample characteristics

	Total sample (N=99)
Female (n, (%))	55 (56.1)
Age (mean (SD); median (IQR))	46.6 (11.3); 47.5 (38.3;55.4)
Ethnicity (n, (%))	
White British	95 (96.0)
Cohabiting (n, (%))	50 (50.5)
Children under 16 (n, (%))	28 (28.3)
Single parent ^a (n, (%))	6 (6.1)
Employed (n, (%))	54 (54.5)
Job status (n, (%))	
A to C1	9 (9.0)
C2 to E (excluding unemployed)	45 (45.5)
Unemployed	45 (45.5)
Age on leaving education (mean (SD); median (IQR))	16.3 (1.9); 16 (15;16)
Age on starting smoking (mean (SD); median (IQR))	14.7 (3.5); 14 (13;16)
Does Partner or other co-habitant smoke? (n, (%))	
Yes	31 (31.3)
No	27 (27.3)
Not applicable	41 (41.4)
BMI (mean (SD), n; median (IQR))	28.1 (6.4), 98; 27.3 (22.4; 32.4)
Indicated mental health problem ^b (n, (%))	41 (41.4)
Duration of smoking (years; mean (SD); median (IQR))	31.9 (12.2); 34.2 (23.3; 42.2)
Previously used SSS (n, (%))	41 (41.4)
Satisfaction with previous use of SSS (if used) (scale 1-11);mean (SD), n	8.3 (2.8), 40

Participant made a quit attempt lasting 24 hours or more in the past year (n, (%))	37 (37.4)
Did the participant cut down before previous cessation? ^c (n, (%))	
Yes	5 (13.5)
No	32 (86.5)
Total n	37
Used cessation aids as part of a quit attempt in previous 12 months ^d (n, (%))	
Yes	29 (78.4)
No	8 (21.6)
Total n	37
Used cessation aids not as part of a quit attempt in previous 12 months (n, (%))	
Yes	21 (33.9)
No	41 (66.1)
Total n	62
Self-reported cigarettes smoked per day (mean (SD); median (IQR))	21.6 (14.3), 19.1 (14.4;24.4)
Expired air CO (ppm), mean (SD)	18.0 (8.0)
FTND (mean (SD); median (IQR))	5.6 (2.0); 6 (4;7)
Readiness to use PA as a way of controlling smoking, ACTION and MAINTENANCE stage (n, (%))	9 (9.1)
Self-reported minutes of moderate and vigorous physical activity over previous 7 days (median (IQR))	315 (120, 540)
Accelerometer data	n=66
Minutes spent in moderate/vigorous/very vigorous activity per day (mean (SD), n; median (IQR))	31.9 (24.5); 28.37 (13.2; 44.8)
Step counts (mean (SD), n; median (IQR))	7701.7 (3536.2); 7343.5 (4909; 9853)

^aAll single parents female apart from one male, recruited through SSS. As a percentage of women (up to aged 47 – the oldest parent with an under 16 year child) the % of female single parents across all recruitment methods was 17%.

^bAnswered ‘moderately’ or ‘extremely’ anxious or depressed to item 5 of the EQ-5D questionnaire.

BMI: Body mass index; CO: carbon monoxide; FTND: Fagerström test for nicotine dependence; IQR: interquartile range; ppm: parts per million; SD: standard deviation

Those recruited via initial invitation letter, compared with those recruited via a follow-up telephone call, were more likely to have used SSS in the past ($X^2(1, N=93) = 4.45, p = 0.035$) and to self-report completing at least 30 minutes of moderate/vigorous PA per day at baseline ($X^2(1, N=92) = 4.45, p = 0.035$), but other variables were not associated with recruitment method.

2.3.3 Recruitment rates and associated researcher time

Invitations sent (with no follow-up telephone calls) led to 5.1% of those invited being randomised into the study. With follow-up telephone calls to non-responders this proportion increased to 8.8%.

Invitations sent from SSS (with no follow-up telephone calls) led to 6.8% of those invited being randomised into the study. With follow-up telephone calls to non-responders this proportion increased to 11.1%.

Based on the figures above and data collected on researcher time dedicated to each recruitment method, to recruit 100 participants (with a 5.1% conversion rate) through primary care (via *letter invitation only* without follow-up) would require 1,961 invitations to be sent and 1,800 minutes (30 hours) of researcher time. To recruit 100 participants via letter invitation and follow-up telephone reminders (8.8% conversion rate) would require 1,336 invitations to be sent and would require 7,134 minutes (118.9 hours) of researcher time.

To recruit 100 participants (with a 6.8% conversion rate) through SSS (via *letter invitation only* without follow-up) would require 1,471 invitations to be sent and 2,400 minutes (40 hours) of researcher time. To recruit 100 participants via letter invitation and follow-up telephone reminders (11.1% conversion rate) would require 901 invitations to be sent and 7,547 minutes (125.8 hours) of researcher time. Further details can be found in *Tables 3 and 4*.

Table 3 Time associated with recruiting 100 participants through Primary Care

	Denominator	To recruit 100 (Letter only – 5.1% response)	To recruit 100 (Letter plus follow up telephone calls – 8.8% response)

Activity	Number	Time (mins)	Number	Time (mins)	Number	Time (mins)
Database searching	Per practice/location	60	<i>Per practice</i>	60	<i>Per practice</i>	60
Initial screening	To produce 200 eligible	60	1961	588	1336	401
Mailing invitations	200	240	1961	2353	1336	1603
GP screening of responses	1	2	100	200	100	200
Associated researcher time	1	18* 145**	100	1800	100	7134

*Letter only. ** Letter plus follow up telephone call

GP: general practitioner

Table 4 Time associated with recruiting 100 participants through Stop Smoking Services

	Denominator		To recruit 100 (Letter only – 6.8% response)		To recruit 100 (Letter plus follow up telephone calls – 11.1% response)	
Activity	Number	Time (mins)	Number	Time (mins)	Number	Time (mins)
Database searching	Per practice/location	60	<i>Per practice</i>	60	<i>Per practice</i>	60
Initial screening	To produce 200 eligible	60	1471	441	901	270
Mailing invitations	200	240	1471	1765	901	1081
GP screening of responses	1	2	100	200	100	200
Associated researcher time	1	24* 157**	100	2400	100	7547

*Letter only. ** Letter plus follow up telephone call

GP: general practitioner

2.3.4 Reasons for ineligibility

The reasons for ineligibility were similar across recruitment methods (*Table 5*).

The main reason for ineligibility (>50% of those ineligible) was due to the individual having already quit smoking. A summary of recruitment via different locations is shown in *Table 6*, and the flow of participants through each recruitment method up to randomisation is shown in Figure 3.

Figure 3 CONSORT diagram showing recruitment approaches and participant flow up to randomisation

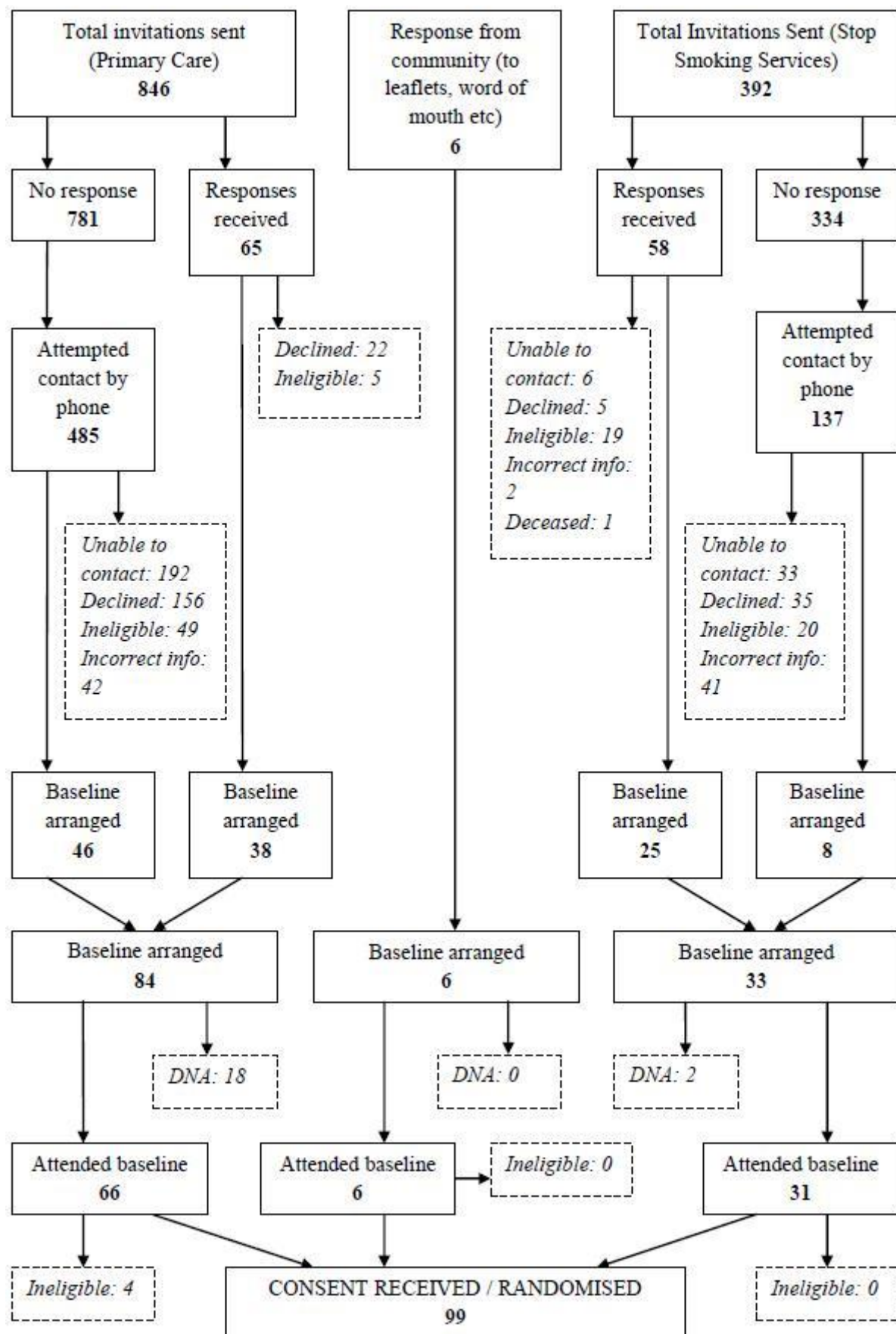


Table 5 Reasons for ineligibility (other community not shown, 0% ineligible)

	Primary Care	SSS
Health/Physical (%)	15.8	20.5
Already quit (%)	57.9	53.8
Smokes <10 cigarettes per day (%)	10.5	10.4
Close friend or relative of somebody already in the trial (%)	0.0	5.1
Currently using NRT (%)	5.3	5.1
Under 18 years (%)	0.0	5.1
Wants to quit immediately (%)	10.5	0.0

NRT: nicotine replacement therapy

Table 6 Participant recruitment by recruitment method

Recruitment method	N=99, n (%)	% of target
Primary care	62 (62.6)	62/60 (103.3%)
<i>Letter only</i>	31 (31.3)	
<i>Letter plus reminder telephone calls</i>	31 (31.3)	
Stop Smoking Services	31 (31.3)	31/30 (103.3%)
<i>Letter only</i>	24 (24.2)	
<i>Letter plus reminder telephone calls</i>	7 (7.1)	
Community (without invitation letter)	6 (6.1)	6/30 (20.0%)

2.3.5 Qualitative observations

A qualitative summary of the variety of other community approaches to recruitment are presented in *Table 7*. The various approaches resulted in only six participants entering the study and had a directly associated researcher time of 469 minutes to recruit one participant. To recruit 100 participants via other community approaches would require 46,900 minutes (781.7 hours) of researcher time.

Table 7 Location and summary of effectiveness of recruitment efforts

WORKPLACE SITE	Relative success and qualitative observations
Local adult education and training provider	Total recruited = 0. Despite being followed up after initial provision of information, nobody came forward expressing interest in the study. Location was identified as an attempt to target the unemployed and low skilled. A general feeling that the information became lost amongst lots of other available information.
Post Office MDEC (Manual Data Entry Centre)	Total recruited = 0. After initial meeting and briefing with the personnel manager, information was distributed at team meetings to all employees (c.500). Despite following up with the personnel manager, nobody came forward expressing an interest. No confirmation of the quality of information that was cascaded to all employees – uncertainty over how well or enthusiastically the information was distributed. Likely to have been a low priority among the managers and a potential burden on their time.
EDUCATIONAL SITE	

Local Primary School	Total recruited = 0. A small article about the study published and distributed to parents within the newsletter failed to attract any interest. Potentially intended to target single parents, but likely to be too broad an approach which people took little notice of as the information became lost amongst other more relevant information in the newsletter. Potentially out of place in the school letter context.
Mother/toddler groups; Several local children's centres	Total recruited = 0. Intended to target single parents as much as possible, the mother and toddler groups consisted of relatively low numbers, not all of whom were smokers. Small amounts of interest were shown, but researchers reported that the mothers' focus was on their children and they were generally not very receptive to the information being offered. Researcher potentially viewed as an 'outsider'.
COMMUNITY SITE/ORGANISATION	
Job Centre (Devonport)	Total recruited = 1. Intended to target the unemployed, 1 person was recruited into the trial from approximately 100 information packs being distributed. Researcher found it to be quite an 'intrusive' activity on people smoking outside the job centre and met some degree of hostility. Reported a sense that people would take the information just to get them to 'go away'. A feeling that people were not very receptive to the information as they were there for other reasons with other pressing concerns. Potentially being viewed as 'an outsider'.
Local community hub cafe	Total recruited = 0. Intended to target the unemployed and low skilled. Researchers reported a feeling that the people attending this location had multiple other serious issues (housing, drug addiction etc.) which made them unreceptive to the information on offer. For most, smoking behaviour was not a high priority.
Local community cooperative organisation	Total recruited = 0. Reports that once the information has been handed over and staff briefed about the study, it would quickly become a low priority among staff given information for distribution.
YMCA (Community run gym)	Total recruited = 0. No idea on the number of smokers actually using the service. Potential again for the enthusiasm for promoting the study to be lost once the information is left with those outside the study team, despite follow ups.
Local Gym	Total recruited = 0. Impression that promoting the study was a very low priority for the gym instructors with no interest being generated.
Local social club	Total recruited = 2. The contact at the small local social club was very proactive and involved with the study. They had their own motivation to promote healthy initiatives to the local community and as such generated interest. The comparative success of this location was reported to be solely due to the individual's motivation for promoting the study and encouraging their service users to take part.
Public Health	Total recruited = 0. Similar reports to other groups where information was left for groups attended by potential participants – not all attending were smokers, and with relatively low numbers attending no interest was generated.
Three Local Housing Associations	Total recruited = 0. Potential for information to be dropped to houses which had already received an invitation via their GP. This type of invitation possibly lacked the 'authority' of the invitation coming directly from their GP.
Neighbourhood Managers (City Council)	Total recruited = 0. It was again reported that whilst enthusiasm was high amongst the neighbourhood managers when meeting with the research team, the study took a very low priority for what is a very busy work force.
Local Community Learning Centre	Total recruited = 0. Intended to target the unemployed and low skilled, it was unpredictable in how many people would attend the sessions at which the researchers provided information and again not all attendees would be smokers. Potentially seen as 'an outsider'.

OTHER	
Local library	Total recruited = 0. No way of knowing how many people read or saw the information on display. Potential for information to become lost amongst swathes of other information.
Heart Radio/Plymouth Sound/Radio Devon/Newspaper	Total recruited = 0. Broad awareness of the study was generated and interest attracted from people too far outside the study areas to be offered inclusion. The approach was not targeted enough at the disadvantaged groups intended.
Word-of-mouth	Total recruited = 0. Proved to be ineffective attracting no interest. Potentially due to lack of motivation on an individual level in promoting the study – potentially could be improved by incentivising referral.
Individual contacts (e.g. minister of religion, local day support facility member, publican)	Total recruited = 1. One person recruited opportunistically through a researcher's local contact. Relatively small reach via this approach and again reliant on individual promotion of study by people outside the study team.
Increasing Access to Psychological Therapies Service, Plymouth	Total recruited = 0. Intended to target those with mental health problems. Systems for recruiting and referring individuals were problematic and at times convoluted (due to data protection). Communication between the research team and IAPT was difficult as there was a sense that the study was a low priority for the practitioners who had other issues to deal with.
Posters displayed around local shops and businesses	Total recruited = 0. Generally reported to be wholly ineffectual, assumed to be due to individuals' lack of motivation to take the initiative and contact the research team directly.

One participant was recruited opportunistically after enquiring at the health centre where the study was based about support services for smokers; another participant was recruited through a friend who had been approached via SSS.

A summary of the characteristics of the participants interviewed at the end of the study can be found in *Table 8*. The novel approach of actively promoting support for reduction in smoking was well received by the majority of the sample. Many emphasised the appeal of reduction against the alternative of stopping abruptly. The appeal of reducing appeared to stem from an underlying desire to change behaviour, but due to a lack of confidence or desire to stop abruptly, reduction seemed a much more manageable objective.

I think that was probably it, the reduction thinking. Well you know, rather than sort of go cold turkey and completely stop I thought, "Oh you know, you could help me reduce it," which you did, so you know that obviously it worked.

(Female, 60-65 years, unemployed, moderate smoker, intervention)

Yeah it did as well, because I thought, "I don't really want to, I am not ready to stop yet," and I thought cutting down is quite good.

(Female, 35-40 years, employed part-time, moderate smoker, control)

For some, past experiences of failed quitting heightened the appeal of support for reduction as a novel approach to tackling their smoking behaviour.

Well, for 3 or 4 years I've been trying to give up smoking [and] last month [I] done 10 months, and then I had a smoke... This one appealed to me because you cut down, you know, every week you cut down two cigarettes a week and you just cut down and cut down and I eventually got down to none.

(Male, 60-65 years, unemployed, moderate smoker, intervention, successful quitter)

The message of support to cut down, in the trial invitation, did not appear to threaten people's sense of control over their own behaviour compared with a message around abrupt quitting. For some, it was clear that a pervading message of the need to 'stop smoking' would have completely alienated them from engaging in the study.

[The researcher] was saying, 'We can help you to cut down. We may in time be able to stop you smoking,' and I said, "Well, that's a very sensible attitude to take," because someone telling me, "I'm going to stop you smoking," I'd tell them to... go away! So that's what made me do it initially, because they weren't threatening me that they could stop me smoking. But even at this time, there is no-one that can tell me, "I can stop you smoking," you know what I mean?

(Male, 55-60 years, unemployed, heavy smoker, intervention)

The invitation was designed, as was the intervention, to be supportive and client-centred and a step away from traditional services, and the supportive and unpressurised nature of the invitation was well received.

You know, I say, when [the researcher] gave me the leaflet I thought, "Yeah, alright, I've heard all this before," and I thought, "Well, here we go

with the hard sell.” But [they were] totally different. [They were] so relaxed, so friendly, and that’s what pushed me towards it. If [they] had tried to come across with the hard sell I would most probably have just ignored [them] and said cheerio. But I think just approaching people in a friendly manner...I mean, sometimes it helps.

(Male, 55-60 years, employed full time, heavy smoker, intervention)

Negative experiences of using NRT and other medicinal therapies emerged as a strong theme linked to motivation for taking part. The intervention was envisaged as a novel alternative to NRT, and people’s description of past experiences seemed to confirm this particular aspect of the intervention.

Oh I’ve tried a couple of times to cut out smoking totally ‘cause I’ve tried the smoking aids and all the things you know, the puffer and the patches and that hasn’t worked, so I thought, “Oh well, I’ll give this a try then try and cut down,” yeah.

(Male, 40-45 years, employed part time, very heavy smoker, intervention)

The appeal of the invitation to reduce smoking, as opposed to quit, was supported by the Health Trainers when interviewed, who identified a desire to reduce smoking as the primary factor when asked “What attracted participants to the study?”.

They’re only coming in because we’ve said reducing smoking, rather than quitting and I think that’s what is getting them into the surgery...

(HT3)

Um, a different approach maybe, slightly different to what they’ve actually done before, and I think it wasn’t about quitting, it’s about trying to reduce rather than them quitting...

(HT2)

Overall, there was a clear indication that the invitation appealed to and reached people who would not have been interested in support to quit.

Table 8 Characteristics of participants who were interviewed at the end of the study

	Control (N=10) (20% of sample)	Intervention (N=15) (30% of initial sample)
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Demographics		
<i>Age (years); mean, SD</i>	46 (11)	52 (11)
<i>Gender (m/f)</i>	5:5	8:7
<i>Job status; n (%)</i>		
A1-C1	0 (0)	0 (0)
C2-E (excluding unemployed)	5 (50)	9 (60)
Unemployed	5 (50)	6 (40)
<i>Single parenthood; n (%)</i>	1 (10)	0 (0)
Baseline data		
<i>Smoking characteristics</i>		
Tobacco (grams/day); mean (SD)	17.4 (8.7) 5.3 (1.9)	18.4 (12.5) 4.9 (1.7)
<i>FTND; mean (SD)</i>		
<i>Self-reported MVPA (minutes/week); mean (SD)</i>	595 (757)	401 (644)
<i>Self-reported MVPA (minutes/week); Range; n (%)</i>		
0	2 (20) 4 (40)	4 (27) 9 (60)
1-499	3 (30)	1 (7)
500-1999	1 (10)	1 (7)
2000+	5 (50)	5 (33)
<i>Quit attempt in past year; n (%)</i>		
Outcomes		
<i>Quit attempt made; n (%)</i>	0 (0)	5 (33)
<i>4 week CO confirmed abstinence; n (%)</i>	n/a	4 (80)
<i>>50% reduction in smoking; n (%)</i>	2 (20)	4 (>33)*
<i>No change in smoking; n (%)</i>	8 (80)	4 (>26)*
		*no data on 50% reduction for 3 participants
Recruitment		
<i>Avenue (GP: SSS: community); n (%)</i>	5:5:0 (50 : 50 : 0)	7:6:2 (47 : 40 : 13)
<i>Type (letter: telephone: other); n (%)</i>	7:3:0 (70 : 30 : 0)	6:7:2 (40 : 47 : 13)

CO: carbon monoxide; FTND: Fagerström test for nicotine dependence; ppm: parts per million; MVPA: moderate and vigorous physical activity; SD: standard deviation

2.4. Discussion

This unique study provides much needed data on the engagement of disadvantaged populations with a focus on harm reduction as opposed to abrupt quitting, and provides a systematic attempt to assess the effects of increasing intensity of recruitment activity (via follow-up telephone calls) and recruitment methods on accessing disadvantaged groups. It is the first to provide likely recruitment rates of such a population into a research trial on PA and smoking reduction.

Recruitment targets were met for the operational definition of a disadvantaged group of 91% in social class C2–E (target 75%), 41% with an indicated mental health problem (target 20%), but failed to reach the proposed target of 30% for single parents (17% of sample). This was a particularly difficult group to target, partly due to this information not being available from GP and SSS databases, and also due to the difficulty in targeting single parents within the community. From the attempts that were made to target this sample within the community (i.e., parent and toddler groups, school settings) no single parents were recruited. More robust and effective methods are needed to understand the best way to engage with single parents who smoke. Since conducting the study we have become aware of several smoking/harm reduction studies (e.g., studies cited in the NICE guidelines on harm reduction, 2013) and these may provide further ideas on how best to recruit single parents. Future ideas for recruitment of single parents may include the use of midwifery records which record the smoking status of antenatal women.

The greatest reason (>50%) for ineligibility was an individual having already quit smoking, although it is possible that potential participants used this as an

excuse for not participating. Records of smoking status, held by both GP practices and SSS, were obviously dated in terms of the last contact at which they were recorded as smoking, thereby increasing the resources needed for inviting and screening.

The sample were overall relatively heavy smokers (with a mean of 20 self-reported cigarettes per day, compared with a national average of 12.7 cigarettes per day (Eastwood, 2013) indicating that the invitation to support reduction can recruit heavier smokers, building on previous survey data (Coleman et al., 2010). The sample self-reported high levels of daily physical activity, averaging more than the recommended 30 minutes of moderate/vigorous activity per day, although objectively measured physical activity suggested that individuals were overestimating their levels of activity (assessed by plotting the difference between mean accelerometer-measured and mean self-reported MVPA by overall mean MVPA derived from the means of both scores, see Taylor et al. (2014) for further details). There is evidence to suggest that this is fairly typical of a disadvantaged population due to higher levels of activity associated with work and active transport (Cerin et al., 2009; Cerin & Leslie, 2008; Roberts et al., 2013; Turrell et al., 2013). The higher levels of activity may also reflect self-selection bias: The trial invitation referred to an intervention which included physical activity and lifestyle support which may have attracted a more active sample. Of those recruited, the gender balance was relatively even and similar to levels of engagement within NHS SSS (West, May, West, Croghan, & McEwen, 2013). Overall, approximately 44% and 56% of all mailed invitations went to males and females respectively, indicating very similar recruitment rates for males (7.7%) and females (7.4%) suggesting the

approach to recruitment and appeal of the invitation is equally effective at recruiting both male and females.

Whilst the use of follow-up telephone calls was effective at increasing recruitment rates, this increased researcher time (and costs) about 5-7 fold per participant recruited. The findings suggest that those recruited via follow-up telephone calls represented a harder to reach population, being both less likely to have used SSS in the past and less physically active. The use of follow-up telephone calls therefore may offer added value in reaching the more service resistant smokers. It is possible that the reach of the intervention was higher than indicated in the recruitment rates presented: potentially anywhere between 10–66% of smokers invited into the study were not interested or eligible due to having a desire to quit (West & Fidler, 2011). For example, if 1,000 invites were sent, but potentially 66% of those invited were not part of the targeted population, the conversion rates of 5.1%-11.1% presented here may in fact represent 11.6%-25.2% allowing for those who were not part of the intended targeted population for recruitment.

Differences were observed in those recruited through primary care and SSS predominantly in terms of smoking history. Those recruited through SSS were more likely to have used cessation aids in the past and more likely to have made a quit attempt in the previous 12 months. Another significant difference was that those invited through SSS were more likely to respond directly to the letter invitation than to the follow-up telephone call. These differences probably reflected a much more motivated group coming through SSS as they had already engaged with a service to help address their smoking behaviour and were likely to have contemplated changing smoking behaviour. Of those

recruited through primary care nearly three quarters (72.6%) had never previously engaged with SSS. When considered alongside differences in previous cessation aid use and previous quit attempts, this finding suggests that those recruited via primary care represented a much harder to reach group of smokers than those who had attended SSS.

The use of an invitation to receive support to cut down, sent out via primary care, could therefore be a valid way of increasing the reach of traditional smoking services. The nature of the invitation itself (not being branded as part of the SSS and offering support to cut down as opposed to quit) may also have played a large part in increasing the interest in participation in the study among those harder to reach smokers, and qualitative data supported this premise. There appears to be value in the invitation as a successful 'smoking cessation induction' approach for those who would not otherwise engage with traditional services.

Other community approaches were generally very unsuccessful, only recruiting six out of a targeted 30 participants. Data collected suggested this was due to three main reasons: first, when information was given to third parties for distribution the effectiveness relied on the individuals' motivation and priority for promoting the study which was frequently low; second, when the researchers took an active role in promoting the study in community-based locations they felt they were viewed as an 'outsider' and treated with some degree of scepticism (as has been shown elsewhere (Sixsmith et al., 2003) and on occasion hostility; and third, the recruitment approach of distributing information in the form of flyers, posters, and public advertisements, all of which relied on the smoker's motivation to directly contact the research team was shown to be

completely ineffective. An additional element restricting the effectiveness of the community-based recruitment approaches was concern over the researchers' personal safety, which restricted the kinds of activity that were deemed appropriate. Our experiences mirrored those of public health outreach workers trying to recruit smokers into SSS to attempt abrupt quitting in the same location a year before the present trial.

Overall, more research is needed about community based recruitment approaches, although the indications from the present study suggest they are likely to be ineffective. Additional time spent with and incentives for community groups could be explored along with enrolling community 'gatekeepers' into the study as part of the research team and promoting partnership working. There is little evidence to suggest that the distribution of information via posters and other community media is effective; the possibility remains that doing so may raise the profile and increase the legitimacy of the research making recruitment via other avenues more likely (Berg, 1999), although this cannot be quantified from the current research.

It is a limitation that the present study did not seek to recruit homeless and other disadvantaged smokers who were not registered with a GP, as well excluding those with serious mental illness (groups demonstrating high levels of smoking) but within the scope of the study this was necessary to ensure adequate screening during recruitment and safety of the research team. Smoking reduction trials may have particular appeal amongst such groups and future research in this area would be appropriate.

Overall, assessing the reach of the current study (in line with the RE-AIM framework (Gaglio, Shoup, & Glasgow, 2013) is problematic due to lack of any

denominator figure for the eligible population from which the sample was derived. Ethical approval was not obtained for profiling those who were invited into the study but did not respond and were not successfully contacted by the research team. A future study should carefully consider ways to address this in order to more firmly establish the 'reach' of the study in terms of accessing the most disadvantaged groups within society.

2.5. Conclusions

This study has demonstrated that using General Practice lists is a powerful way of recruiting patients to health interventions in an area of deprivation, and much more effective than community approaches. More than 98% of people in the UK in all areas are registered with a GP and on average visit 5.3 times per year (Hippisley-Cox & Vinogradova, 2009). People trust information provided via their GP more than other sources (Royal College of General Practitioners, 2013) and this almost certainly was the reason for the much higher response rate. The methods employed successfully recruited a disadvantaged population against a predefined criteria, with further research needed on how best to recruit single parents. The addition of follow-up telephone calls does increase the recruitment rate, but at a considerable cost. Recruitment of a strongly service resistant group may be possible through invitation from GP practices than with nearly three quarters of those recruited having never accessed specialist stop smoking services before. Qualitatively, the message of smoking reduction (as opposed to smoking cessation) is a powerful tool in accessing those who may not have otherwise engaged with any form of smoking services. This research provides important and pragmatic information for the future recruitment of disadvantage populations into research trials.

3. FACTORS ASSOCIATED WITH STUDY ATTRITION IN A PILOT RANDOMISED CONTROLLED TRIAL TO EXPLORE THE ROLE OF EXERCISE ASSISTED REDUCTION TO STOP (EARS) SMOKING IN DISADVANTAGED GROUPS

3.1. Background

Participant attrition within research trials poses a threat to internal validity (attrition bias) (Leeman et al., 2006), external validity (retained participants may not reflect practice) and loss of statistical power (reduced number of participants). Strategies to minimise attrition may also have implications for the cost of conducting trials due to additional researcher time necessary to capture follow-up data. Pilot trials can help to identify factors associated with study attrition and provide valuable information for the planning of a definitive trial.

It is usual for smoking cessation intervention trials to utilise intention to treat (ITT) analyses with an assumption that a participant lost to follow-up is still smoking (baseline observation carried forward) (West, Hajek, Stead, & Stapleton, 2005). This assumption is problematic, as it could bias results and statistical tests in favour of an effective treatment if attrition rates are higher in the control group, as there is some evidence to suggest that those lost to follow-up in such trials may not necessarily be smoking (Borland, Balmford, & Hunt, 2004; Kaper, Wagena, Willemsen, & van Schayck, 2005; Nevid & Javier, 1997; Stockton, McMahon, & Jason, 2000; Twardella & Brenner, 2007). Different approaches to handling missing data on smoking status at follow-up have been suggested, which may provide more reliable estimates of treatment effects (Barnes, Larsen, Schroeder, Hanson, & Decker, 2010; Hedeker, Mermelstein, &

Demirtas, 2007; Twardella & Brenner, 2008). However, all approaches rely on making assumptions about the missing data. It is therefore important to understand the factors influencing attrition to allow for more informed approaches to handling missing data (understanding the potential mechanism behind the “missingness”, e.g. is the data missing at random, missing not a random, missing completely at random to inform the choice of analyses incorporating missing data), and to identify ways to minimise attrition in future smoking studies. Whilst it could be argued that addressing recruitment approaches to recruit a population less likely to withdraw could be a solution, this will limit the recruitment to a very specific group, therefore limiting the scope of recruitment into a trial and perpetuating issues around generalisability of recruitment as highlighted in the previous chapter, This could be especially true of trials involving low socioeconomic groups where attrition rates may be greater than for other groups.

Studies involving interventions to support ‘abrupt’ smoking cessation report a wide range of attrition rates. In a review of RCTs of individual behavioural counselling interventions for smoking cessation (Lancaster & Stead, 2005) attrition rates (where reported) ranged from 1.7% (Kim, Lee, Hwang, & Lee, 2005) to 22.4% (Rigotti et al., 1997) at 6 months’ follow-up and from 3% (Simon, Carmody, Hudes, Snyder, & Murray, 2003) to 31% (Aveyard et al., 2007) at 12 months’ follow-up. A review of RCTs of interventions combining behavioural counselling and pharmacological support (Stead & Lancaster, 2012) identified a range of attrition rates from as low as 4–8% (Katz, Muehlenbruch, Brown, Fiore, & Baker, 2004) in one study and up to 24–30% (Chan et al., 2010) in another at 6-months’ follow-up, and between 7% (Segnan et al., 1991) to 52% (Binnie, McHugh, Jenkins, Borland, & Macpherson, 2007)

at 12 months' follow-up in two other studies. Although one study identified in the review saw an attrition rate < 5% at 24 months' follow-up (Mohiuddin et al., 2007) it targeted in-patients with acute coronary syndrome who were probably more accessible for follow-up, compared with participants in the community. In contrast, a review of self-help interventions for smoking cessation (Lancaster & Stead, 2005), representing the least intensive level of intervention, included studies with attrition rates ranging from 11% (Dijkstra, De Vries, & Roijackers, 1999) to 66% (Nollen et al., 2007) at 6 months' follow-up and <10% (Becona & Vazquez, 2001) to 56% (Strecher et al., 2005) at 12 months' follow-up.

Despite there being 60 systematic reviews on the Cochrane Database on the effectiveness of interventions for smoking cessation (Twardella & Brenner, 2007), little attention has been given to identifying the factors associated with study attrition. The factors associated with attrition in studies concerned with smoking reduction or involving disadvantaged smokers (Bryant et al., 2011; Ranney et al., 2006) are particularly poorly understood, due to a small number of such studies.

A number of factors may influence attrition including: (i) the nature of the intervention (e.g., clinical trials of an investigational medicinal product (CTIMPs) versus clinical trials of complex behavioural interventions (non-CTIMPs); (ii) the population characteristics (e.g., socioeconomic status, demographics); (iii) the study design (e.g., length of time to follow-up, burden of data collection on participant); and (iv) specifically among smoking trials, a focus on abrupt smoking cessation versus smoking reduction.

Smoking reduction is increasingly recognised as a viable alternative to the traditional abrupt smoking cessation approach, with flexible outcome measures

(Collins et al., 2011), and it is unclear if there is any difference between these approaches on attrition. A review comparing interventions involving smoking reduction or abrupt cessation (Lindson-Hawley et al., 2012) included ten studies with attrition rates ranging from 19.1% (Cummings, Emont, Jaen, & Sciandra, 1988) to 21-24% (Hughes, Solomon, Livingston, Callas, & Peters, 2010) at 6 months, and 11-13% (Etter, Huguelet, Perneger, & Cornuz, 2009) to 64% (Curry, Marlatt, Gordon, & Baer, 1988) at 12 months but there appeared to be no difference in attrition between those reducing their smoking before quitting or stopping abruptly.

Exercise as an aid to smoking cessation has been acknowledged as a feasible intervention for supporting cessation, yet the number of rigorous studies remains limited: There were only 15 studies included in the latest Cochrane review on the topic (Ussher et al., 2012), 7 of which included fewer than 25 participants. Of the studies identified in this review, attrition rates varied from 0.3% (J. S. Hill, 1985) to 60.8% (McKay, Danaher, Seeley, Lichtenstein, & Gau, 2008) at 6 months and from 0.5% (Marcus, Albrecht, Niaura, Abrams, & Thompson, 1991) to 68-75% (Marcus et al., 2005) at 12 months. The heterogeneity of research designs and methods among these studies makes it difficult to identify any factors associated with attrition, but attrition rates seem high compared with other studies involving interventions for smoking cessation.

There are few studies on the effectiveness of interventions for smoking cessation among low socioeconomic groups. In a recent review of low income groups and health-behaviour change interventions (Michie, Jochelson, et al., 2009) only 13 studies were identified, and of those only 7 targeted smoking behaviour, and no studies examined potential predictors of and reason for study

attrition. None of the identified studies focussed on smoking reduction among low socioeconomic groups.

Some authors suggest that attrition rates are generally higher in the control condition (Barnes et al., 2010; Hedeker et al., 2007; Twardella & Brenner, 2008), but in the literature we reviewed some studies showed greater attrition in the control or intervention arm, and the majority showed no difference between trial arms. A meta-analysis of a random sample of 100 randomised controlled trials (RCTs) published in medical journals (with a range of participants and interventions) also showed no differential attrition between intervention and control conditions (Crutzen, Viechtbauer, Kotz, & Spigt, 2013).

Several factors have been associated with increased attrition in smoking trials among various populations, including a higher Fagerström Test for Nicotine Dependence (FTND) score (Wennike, Danielsson, Landfeldt, Westin, & Tonnesen, 2003), a lower intention to quit (Dijkstra, De Vries, & Roijackers, 1998), low self-efficacy and a longer smoking history (Dijkstra et al., 1999), and the number of cigarettes smoked per day (Bowen, McTiernan, Powers, & Feng, 2000; Curtin, Brown, & Sales, 2000; Humerfelt, Eide, Kvale, Aaro, & Gulsvik, 1998). It is commonly believed that attrition within smoking cessation studies is driven by failure to maintain a successful quit attempt, where the individual will no longer seek support once they have reinitiated smoking as it holds no value of they are smoking again. This is likely why factors associated with failing to quit (such as level of addiction and dependence) are related to attrition. Less is known in relation to failure to reduce as a predictor of attrition.

The aim of this study is to identify the factors associated with participant attrition in a pilot RCT on the effectiveness of a novel Exercise Assisted Reduction then Stop (EARS) intervention (HTA no. 07/78/02, ISRCTN 13837944, UKCRN Study ID 8937) among disadvantaged smokers. The specific objectives are to determine if features of the trial design and methods, and participant characteristics, are associated with participant attrition, to inform the design and methods for a definitive trial.

3.2. Methods

3.2.1. Participants

Ethical approval for the study was granted by the NHS National Research Ethics Service Committee South West, in the UK (see *Appendix 1*). Recruitment took place in the neighbourhoods of Devonport and Stonehouse (Plymouth, UK) which are among the 3% most deprived areas in the UK. The recruitment methods, factors influencing recruitment, and baseline characteristics of the sample, have been reported elsewhere (Taylor et al., 2014). In summary, 99 adult moderate to heavy smokers, who wanted to reduce smoking (without NRT) but had no plans to quit in the next month, were recruited by either a mailed invitation from their general practitioner or NHS Stop Smoking Services (SSS), with follow-up telephone calls, or through other community approaches.

3.2.2. Procedures

After providing informed consent and baseline information, participants were randomised to receive either usual care (consisting of brief advice on smoking cessation services) or usual care plus the EARS intervention (consisting of up to 12 weekly client-centred individual support sessions, via telephone or in

person, to assist with making self-directed changes in smoking and physical activity behaviour). Participants in either arm of the trial expressing the desire to quit were offered the chance to be referred to local SSS for specialist support.

Follow-up assessments were completed at 4, 8, and 16 weeks post-randomisation. For those who missed follow-up appointments, up to five attempts were made by telephone to reschedule the appointment; the rescheduled appointment could take place up to the halfway point between the missed appointment and the next follow-up. After the halfway point attempts were made to schedule the next follow-up appointment. Those who could not be contacted at all were classified as having dropped out of the study. Reasons for withdrawal were recorded for those who explicitly withdrew consent to participate in the study.

3.2.3. Measures

At baseline the following data were collected: participant demographic information (i.e. age, sex, marital status, cohabiting with other smokers, parental status (single parent living with a dependent under 16 years of age), employment status (employed or not), job status (social class), age of leaving full time education, ethnicity, weight, and height), smoking history (age participant started smoking, longest period of cessation in last year, attempts at cutting down, cessation aids used in past year, use of SSS), number of cigarettes being smoked per day, Fagerström Test for Nicotine Dependence (FTND; (Fagerstrom, 2012; Heatherton et al., 1991) scores, stage of readiness to use physical activity to control smoking behaviour, expired air carbon monoxide (CO), and physical activity data (subjectively by self-report of the previous 7 days and objectively by accelerometer (collected using a tri-axial

GT3X accelerometer (Actigraph, Pensacola, USA) using a 1 sec epoch, over a seven day period and categorized into intensities of activity using established cut-points (Freedson, Melanson, & Sirard, 1998)). Follow-up assessments captured data on smoking and physical activity related behaviours and attitudes. In order to ensure compliance with wearing and returning accelerometers (costing c. £250 each) we initially paid participants £10 for returning the accelerometer at each time point (except week 4 when they were not worn). This was increased to £30 at each time point when it was observed a considerable number had not been returned about a third of the way through the study. No other payment was made to participants for completing assessments other than reimbursing travel expenses. For the purposes of the present study, withdrawal before final follow-up (week 16) was the primary binary outcome. We also classified participants as dropping out early or late: Early dropouts were those who did not complete any assessment after baseline, and late dropouts were those who failed to complete follow-up assessments after week 4. Field notes were maintained to capture qualitative reasons for attrition as reported by withdrawing participants and as observed by researchers.

3.2.4. Data analysis

To determine the factors associated with study attrition at 16 weeks, binary logistic regression was performed and odds ratios reported with 95% confidence intervals. Intervention arm, method of recruitment, participant demographics, and lifestyle, behavioural, and attitudinal characteristics were individually examined as determinants of attrition, based on existing literature and the researchers' a priori reasons for their inclusion. Following the univariable analyses, each significant predictor of attrition was then added to

multivariable logistic regression. Further exploratory analysis sought to compare those who dropped out earlier (before week 4), later (after week 4), or completed the study. Attrition status (early dropout, late dropout or completion) was analysed using multinomial logistic regression, with inclusion of each covariate individually in a separate univariable model, followed by the inclusion of the variables related to attrition in a multivariable multinomial logistic regression model. Multinomial logistic regression was chosen in place of ordinal logistic regression as the three categories were considered to be qualitatively different and not necessarily sequential.

Additional exploratory analyses examined change in cigarettes smoked per day (and therefore the success of individual change) as a predictor of dropout. For those who were followed up at least once post baseline, two categorical variables of at least a 50% reduction and any positive reduction from baseline to week 4 and week 8 were coded and analysed through univariable binary logistic regression in relation to withdrawal before week 16. Analyses exploring possible effects modifications and interactions were not completed due to the limited numbers.

All statistical analyses were completed using Stata SE (v. 12.0). For example STATA commands and outputs highlighting the procedures and order in which the variables were introduced see *Appendix 2*.

3.3. Results

The overall sample characteristics for the 99 participants recruited and randomised have been reported elsewhere (Taylor et al., 2014). Data were collected from 61.6% (n=61) at 16 weeks post baseline. Study attrition occurred

primarily soon after baseline with 21 of the 38 participants lost to follow-up not completing the week 4 assessment.

Table 9 shows that for the sample as a whole those with high self-reported confidence to quit in the next 6 months (n=48) were less likely to withdraw than those with low confidence. Also, those completing at least 150 minutes of moderate and vigorous physical activity (MVPA) per week (n=69) were also less likely to withdraw.

Table 9 Summary of logistic regression analysis for study dropout vs. completion

	Variable	n	Odds Ratio (95% CI)
Methods	<i>Trial Arm^a</i>		
	Intervention	49	1.03 (0.46; 2.32)
	<i>Recruitment Avenue^b</i>		
	Stop Smoking Services	31	0.81 (0.33; 1.99)
	Community	6	0.74 (0.13; 4.35)
	<i>Recruitment Method^c</i>		
	Letter plus telephone reminder	38	2.24 (0.95; 5.26)
	Community	6	1.12 (0.19; 6.70)
Demographics			
	<i>Age (years)</i>	99	0.97 (0.93; 1.01)
	<i>Gender^d</i>		
	Female	56	1.55 (0.68; 3.56)
	<i>Body mass index</i>	98	1.01 (0.95; 1.07)
	<i>Employment Status^e</i>		
	Unemployed	45	1.13 (0.50; 2.55)
	<i>Job Status^f</i>		
	C2-D	45	1.21 (0.27; 5.50)
	Unemployed	45	1.33 (0.29; 6.03)
	<i>Age left education</i>	99	0.93 (0.73; 1.17)

Smoking related variables	<i>Years smoking</i>	99	0.98 (0.94; 1.01)
	<i>Previous use of Stop Smoking Services^g</i>		
	Have not used Stop Smoking Services in the past	58	1.14 (0.50; 2.60)
	<i>Cigarettes per day</i>	99	1.00 (0.97; 1.03)
	<i>Expired air carbon monoxide (parts per million)</i>	98	1.04 (0.99; 1.09)
	<i>Fagerström Test for Nicotine Dependence</i>	99	1.19 (0.96; 1.46)
	<i>Importance of quitting next 6 months (median)^h</i>		
	High importance	49	1.23 (0.54; 2.76)
	<i>Confidence to quit in the next 6 months (median)ⁱ</i>		
	High confidence	48	0.43 (0.19; 0.99)
	<i>Confidence to cut down by half in the next month (median)^j</i>		
	High confidence	39	1.44 (0.63; 3.28)
Physical Activity related variables	<i>Self-reported ≥30 minutes of moderate and vigorous physical activity per day^k</i>		
	Yes	65	0.48 (0.20; 1.12)
	<i>Self-reported minutes of moderate and vigorous physical activity per day</i>	99	1.00 (0.99; 1.00)
	<i>Self-reported ≥30 minutes moderate and vigorous physical activity on at least 5 days^l</i>		
	Yes	43	0.77 (0.34; 1.75)
	<i>Self-reported ≥150mins moderate and vigorous physical activity per week^m</i>		
	Yes	69	0.33 (0.14; 0.81)
	<i>Accelerometer ≥30 minutes moderate and vigorous physical activity per dayⁿ</i>		
	Yes	32	1.11 (0.42; 2.95)
	<i>Accelerometer minutes moderate and vigorous physical activity per day</i>	66	1.00 (0.98; 1.02)
	<i>Stage of change to use physical activity to control smoking^o</i>		
	Planning, action, maintenance	20	0.42 (0.15; 1.40)
	<i>Confidence to exercise for ≥30 minutes on most days over next 6 months^p</i>		

	High confidence	55	0.83 (0.37; 1.86)
	<i>Confidence to walk for ≥15 minutes at a brisk pace^q</i>		
	High confidence	59	1.06 (0.47; 2.43)
	<i>Indicated mental health problem^r</i>		
	Yes	41	1.49 (0.65; 3.38)

^a Reference: control; ^b Reference: Primary care; ^c Reference: letter only; ^d Reference: male; ^e Reference: employed; ^f Reference: social class A–C1; ^g Reference: have used SSS in the past; ^h Reference: low importance; ⁱ Reference: low confidence; ^j Reference: low confidence; ^k Reference: not reporting 30 mins MVPA per day; ^l Reference: not completing 30 mins MVPA on at least 5 days per week; ^m Reference: not reporting >150 mins MVPA per week; ⁿ Reference: not completing 30 mins MVPA per day as assessed by accelerometer; ^o Reference: pre-contemplation and contemplation; ^p Reference: low confidence; ^q Reference: low confidence; ^r Reference group: no indicated mental health problem

The multivariable binary logistic regression of variables found to be related to attrition in the univariable analyses are shown in *Table 10*. In the presence of other variables, only the completion of 150 minutes of moderate and vigorous physical activity (MVPA) per week or more was related to a lower odds ratio of study withdrawal.

Table 10 Multivariable binary logistic regression analysis for study completion vs study drop-out (N=97)

Variable	n	Odds Ratio (95% CI)
<i>Self-reported ≥150 minutes of moderate and vigorous physical activity per week^a</i>		
Yes	47	0.32 (0.13; 0.80)
<i>Confidence to quit in the next 6 months (median)^b</i>		
High (4-7)	34	0.43 (0.18; 1.03)

^a not reporting >150 mins MVPA per week; ^b Reference: Low confidence

Table 11 presents descriptive data of the continuous variables between early dropouts, late dropouts and completers. Age, confidence to quit, and smoking history appeared to vary by withdrawal status; younger people, those with lower confidence to quit in the next 6 months, and those with shorter smoking history seemed more likely to drop out early. There also appeared to be a trend for those dropping out early in the study to have left education later and to have reported lower baseline expired air CO value than those dropping out later.

The odds of participant dropout late in the study (vs completion) were increased for those recruited via follow-up telephone calls (*Table 12*). Greater confidence to quit in the next 6 months was associated with lower odds of late dropout vs. completion compared with lower confidence. With increasing age, the odds of early dropout vs. completion were reduced, but age did not appear to be associated with odds of late dropout vs. completion; years of smoking showed a similar association with both early and late dropout vs. completion. Those who reported doing 150 minutes or more of MVPA per week at baseline had lower odds of early dropout compared with participants who did not complete at least 150 minutes of MVPA per week; however, no equivalent association was found with regard to late dropout.

Table 11 Comparison of continuous baseline variables by early dropouts, late dropouts, and study completers

	N	Early dropout (before Week 4)	Late dropout (after Week 4)	Completer
Age (years); mean (SD), n	99	40.9 (10.2), 21	48.2 (10.7), 17	48.1 (11.4), 61
Age left education (years); mean (SD); median (IQR), n	99	16.5 (1.3); 16 (16; 17), 21	15.7 (0.9); 15 (15; 16), 17	16.4 (2.2); 16 (15;16)
BMI; mean (SD); median (IQR), n	98	29.0 (7.9); 28.0 (23.2; 33.3), 21	27.5 (5.7); 27.3 (22.1; 32.6), 17	28.0 (6.0); 27.0 (22.5; 31.7) , 60
Years smoking; mean (SD); median (IQR), n	99	25.3 (11.9); 27.7 (12.6; 31.8), 21	35.2 (11.6); 37.4 (24.6; 44.7), 17	33.3 (11.9); 35.8 (23.4; 43.1), 61
CPD (n); mean (SD); median (IQR), n	99	19.2 (7.6); 19.8 (13.3; 27.8), 21	23.7 (21.2); 19.6 (15.0; 27.8), 17	21.8 (13.8); 18.9 (15.0; 23.9), 61
CO (ppm); mean (SD); median (IQR), n	98	17.9 (10.0); 14 (11; 21), 21	21.6 (5.2); 21.5 (17.5; 24), 16	17.1 (7.8); 16 (12; 22), 61
FTND; mean (SD), n	99	5.7 (1.8), 21	6.4 (2.2), 17	5.3 (2.1), 61
Self-reported MVPA per day (minutes); mean (SD); median (IQR), n	99	72.3 (91.0); 42.1 (0; 109.3), 21	43.33(49.3); 34.3 (0; 111.4), 17	81.0 (98.6); 47.1 (77.1; 25.7), 61

Accelerometer MVPA per day (minutes); mean (SD); median (IQR), n	66	29.3 (20.4); 27.6 (13.2; 42.5), 19	41.3 (32.8); 35.3 (16.3; 44.9), 9	31.0 (24.3); 25.8 (11.8; 43.7), 38
Importance of quitting in next 6 months; mean (SD); median (IQR), n	99	5.4 (1.5); 6 (4;7), 21	5.1 (2.0); 6 (4;7), 17	5.3 (1.7); 5 (5; 7), 61
Confidence to quit in next 6 months; mean (SD), n	97	3.1 (1.4), 21	2.7 (1.5), 17	3.9 (1.7), 59

IQR: Interquartile range; SD: Standard deviation; MVPA: Moderate and vigorous physical activity

Table 12 Summary of Multinomial logistic regression analysis for study completion status: late/early dropout vs. completion

		Early dropouts (before Week 4)		Late dropouts (after Week 4)	
	Variable	n	Odds Ratio (95% CI)	n	Odds Ratio (95% CI)
	<i>Trial Arm^a</i>				
	Intervention	9	0.78 (0.29; 2.10)	10	1.43 (0.50; 4.39)
Recruitment	<i>Recruitment Avenue^b</i>				
	Stop Smoking Services	6	0.79 (0.26; 2.39)	5	0.84 (0.26; 2.77)
	Community	1	0.66 (0.07; 6.42)	1	0.84 (0.08; 8.33)
	<i>Recruitment Method^c</i>				
	Telephone	9	1.63 (0.58; 4.62)	10	3.32 (1.05; 10.60)
	Community	1	0.86 (0.87; 8.58)	1	1.58 (0.15; 16.61)
Demographics	<i>Age (years)</i>	21	0.94 (0.90; 0.99)	17	1.00 (0.95; 1.05)
	<i>Gender^d</i>				
	Female	13	1.48 (0.53; 5.05)	11	1.67 (0.54; 5.05)
	<i>Body mass index</i>	21	1.02 (0.95; 1.11)	17	0.99 (0.33; 1.08)
	<i>Employment Status^e</i>				
	Unemployed	7	0.63 (0.22; 1.79)	11	2.32 (0.76; 7.03)

	<i>Job Status^f</i>				
	C2-E	13	2.77 (0.30; 25.53)	4	0.43 (0.06; 2.92)
	Unemployed	7	1.55 (0.16; 15.18)	11	1.22 (0.21; 7.03)
	<i>Age left education</i>	21	1.04 (0.82; 1.31)	17	0.64 (0.36; 1.14)
Smoking history					
	<i>Years smoking</i>		0.95 (0.90; 0.99)		1.16 (0.97; 1.06)
	<i>Previous use of Stop Smoking Services^g</i>				
	No	14	01.49 (0.53; 4.22)	9	0.84 (0.28; 2.46)
Smoking related variables					
	<i>Cigarettes per day</i>	21	0.82 (0.94; 1.03)	17	1.01 (0.97; 1.04)
	<i>Expired air carbon monoxide (parts per million)</i>	21	1.01 (0.95; 1.08)	16	1.07 (1.00; 1.14)
	<i>Fagerström Test for Nicotine Dependence</i>	21	1.01 (0.86; 1.42)	17	1.31 (0.98; 1.73)
	<i>Importance of quitting in the next 6 months (median)^h</i>				
	High 6-7	11	1.21 (0.45; 3.29)	9	1.24 (0.42; 3.63)
	<i>Confidence to quit in the next 6 months (median)ⁱ</i>				
	High 4-7	12	0.55 (0.20; 1.51)	10	0.31 (0.95; 0.98)
	<i>Confidence to cut down by half in the next month (median)^j</i>				
	High 5-7	3	1.95 (0.71; 5.31)	2	0.97 (0.31; 2.97)

Physical Activity related variables	<i>Self-reported ≥30 minutes of moderate and vigorous physical activity per day^k</i>				
	Yes	11	0.42 (0.15; 1.19)	10	0.55 (0.18; 1.68)
	<i>Self-reported minutes of moderate and vigorous physical activity per day</i>	21	1.00 (0.99; 1.00)	17	0.99 (0.98; 1.00)
	<i>Self-reported ≥30minutes of moderate and vigorous physical activity on at least 5 days^l</i>				
	Yes	9	0.89 (0.33; 2.41)	6	0.64 (0.21; 1.95)
	<i>Self-reported ≥150 minutes of moderate and vigorous physical activity per week^m</i>				
	Yes	11	0.30 (0.10; 0.85)	10	0.39 (0.12; 1.21)
	<i>Accelerometer ≥30 minutes of moderate and vigorous physical activity per dayⁿ</i>				
	Yes	8	0.81 (0.27; 2.46)	6	2.23 (0.48; 10.18)
	<i>Accelerometer total minutes of moderate and vigorous physical activity per day</i>	19	1.00 (0.97; 1.02)	9	0.54 (0.99; 1.04)
	<i>Stage of change to use physical activity to control smoking^o</i>				
	Planning, action, maintenance	2	0.32 (0.07; 1.55)	3	0.66 (0.17; 2.61)
	<i>Confidence to exercise for ≥30 minutes on most days over next 6 months^p</i>				
	High (6-7)	12	0.99 (0.36; 2.69)	8	0.66 (0.23; 1.93)
	<i>Confidence to walk for ≥15 minutes at a brisk pace^q</i>				
	High (7)	12	0.46 (0.34; 2.53)	11	1.27 (0.41; 3.90)

	<i>Indicated Mental Health problem^r</i>				
	Yes	11	1.82 (0.67; 4.95)	7	1.16 (0.39; 3.46)

^a Reference: control; ^b Reference: Primary care; ^c Reference: letter only; ^d Reference: male; ^e Reference: employed ;^f Reference: social class A-C1; ^g Reference: have used SSS in the past; ^h Reference: low importance; ⁱ Reference: low confidence; ^j Reference: low confidence; ^k Reference: not reporting 30 mins MVPA per day; ^l Reference: not completing 30 mins MVPA on at least 5 days per week; ^m Reference: not reporting >150 mins MVPA per week; ⁿ Reference: not completing 30 mins MVPA per day as assessed by accelerometer; ^o Reference: pre-contemplation and contemplation; ^p Reference: low confidence; ^q Reference: low confidence; ^r Reference group: no indicated mental health problem

Variables shown to be related to attrition in the univariable multinomial analyses were carried forward into a multivariable multinomial analysis and are shown in *Table 13*. Only the completion of 150 minutes of MVPA per week or more retained any significance in the presence of the other variables, with those completing more than 150 minutes of MVPA per week at baseline being less likely to withdraw early than later in the study when compared to study completers.

Table 13 Multivariable multinomial logistic regression for study completion status: late/early dropout vs completion (N=97)

Variable	Early dropouts (before Week 4)		Late dropouts (after Week 4)	
	n	Odds Ratio (95% CI)	n	Odds Ratio (95% CI)
<i>Self-reported ≥150 minutes of moderate and vigorous physical activity per week^m</i>				
Yes	11	0.23 (0.07; 0.75)	10	0.52 (0.14; 1.90)
<i>Confidence to quit in the next 6 months (median)ⁱ</i>				
High (4-7)	9	0.50 (0.16; 1.51)	5	0.37 (0.11; 1.27)
<i>Recruitment Method^c</i>				
Telephone	9	1.25 (0.39; 4.01)	10	2.77 (0.79; 9.78)
Community	1	0.51 (0.42; 6.17)	1	1.72 (0.14; 21.33)
<i>Age (years)</i>	21	1.00 (0.85; 1.17)	17	0.84 (0.65; 1.06)
<i>Years smoking</i>	21	0.94 (0.81; 1.09)	17	1.21 (0.95; 1.54)

^a Reference: not reporting >150 mins MVPA per week; ^b Reference: Low confidence; ^c Reference: Letter only

Exploratory analyses of change in cigarettes smoked per day (from baseline to either week 4 or week 8), shown in *Table 14*, showed no significance in predicting study dropout before week 16.

Table 14 Logistic regression of study attrition for change in cigarettes smoked per day before week 16 (N=78) (late dropout vs completion)

Variable	n	Odds Ratio (95% CI)
<i>Reduction of 50% or more before week 16</i>		
Yes	28	0.31 (0.08; 1.19)
<i>Any reduction in cigarettes smoked per day before week 16</i>		
Yes	58	0.55 (0.17; 1.74)

Qualitative reasons for withdrawal were not possible to obtain directly from participants whom we were unable to contact. Of those who explicitly withdrew consent (n=15), the reasons for dropout included illness or death of a close family member, advice from a mental health care worker that the participant had become anxious about involvement in the study, time pressures elsewhere, expecting a greater financial reward for taking part (indicating a possible misunderstanding of study procedures due to poor explanation), and being dissatisfied with allocation to the control condition.

3.4. Discussion

The overall attrition rate of 38.4% at 16 weeks falls within the range of attrition rates identified in other broader trials of smoking cessation. In the absence of similar studies, the overall retention in this study could be regarded as acceptable for a group of disadvantaged smokers and provides valuable information for a larger study. Unlike some trials we did not explicitly pay

participants to complete follow up assessments and one may assume a lower attrition rate had we done so.

The analysis consisted of multiple testing which inherently raises the risk of a type I error (findings of false significance) and implicates a necessary adjustment to the set p-value for when attributing significance to findings (Feise, 2002; Zhang, Quan, Ng, & Stepanavage, 1997), however due to the pilot nature of the study and the sample not being powered to adequately detect significant results, no adjustments have been considered nor any p-values presented.

The fact that over 50% of those dropping out did so before week 4 suggests that particular focus is needed on new ways to maintain participation in the initial stages of trial engagement. Although attrition in both treatment arms was the same in the present study, it may be that the predictors of attrition may vary between arms. However, the numbers in this pilot trial were insufficient to inferentially test this hypothesis.

The only trial design factors which may influence attrition were whether or not participants were recruited by follow-up telephone call; those recruited by this more intensive approach were more likely to drop out later than earlier in the study, possibly reflecting ambivalence to the invitation. We deliberately conducted follow-up telephone calls to recruit smokers in case they had low literacy levels. It may be that providing further data after baseline was too challenging and we should consider providing more support to keep these individuals in the study. Recruitment via different locations (primary care vs. SSS), and the method of recruitment, also showed no effect on attrition in the sample as a whole. We found equal attrition in both the intervention and control arms, which has been reported elsewhere (Crutzen et al., 2013).

The mean age of those dropping out early in the study was younger than the mean age of those completing the study. Age has been reported elsewhere to predict attrition, with older participants less likely to drop out (Fortmann & Killen, 1994), suggesting they may be more committed and able to have more time to remain in a trial (Leeman et al., 2006). This highlights the need for additional support for engaging younger people. However, other studies have not found age to be related to attrition (Curtin et al., 2000; Nevid & Javier, 1997). No other participant demographic characteristics showed evidence of any relationship with study attrition. Our researchers worked flexible hours to conduct assessments with participants (in employment or not), and this may have reduced the risk of attrition.

We were interested in whether we could retain more dependent and heavier smokers in the trial. The finding that those with a longer smoking history and a trend for smoking more cigarettes were more likely to complete the study was encouraging. They may suggest that a trial focussed on cutting down may be more appealing to heavier smokers, a finding reported elsewhere (Shiffman et al., 2007). In contrast it appeared that those with greater confidence to quit (normally associated with lower dependence) were less likely to withdraw, specifically, less likely to withdraw later in the study. These preliminary contrasting findings are not easy to explain but it would appear that future researchers should stress that smoking behaviour and related beliefs (such as confidence to quit) should not influence continued participation in a trial.

In smoking cessation studies, smoking relapse is typically associated with attrition and, similarly, it may be that a failure to reduce smoking levels is associated with attrition. Also, several of the variables shown to predict attrition

in the present study are the same as those that predict smoking relapse (e.g. low self-efficacy, lower age) and there may be a common set of variables that predict smoking relapse, failure to reduce and attrition. There may also be variables that are specific to smoking reduction versus cessation studies. For example, a higher level of cigarette dependence reliably predicts smoking relapse (Vangeli et al., 2011) but in the current study higher dependence was associated with less attrition.

Those who completed at least 150 minutes of MVPA per week at baseline were also less likely to withdraw than those reporting less activity; specifically, these participants were less likely to withdraw early in the study. This finding remained significant even in the presence of other predictor variables in the multivariable model. This replicates the findings from another study in which those who were inactive at baseline were significantly more likely to drop out of an arm of a trial with a focus on fitness training (Lowther, Mutrie, & Scott, 2002). Greater study attrition among less active participants in a physical activity study has the potential to reduce the size of effects due to a ceiling effect. It also poses a threat to external validity if the findings cannot be generalised to less active populations. Other research involving low socioeconomic groups on the effectiveness of a physical activity intervention (Lowther et al., 2002) reported that attrition rates were significantly higher in those randomised to a 'fitness assessment' intervention compared with an 'exercise consultation' intervention. This suggests that intervention content may differentially influence attrition. The present study involved PA counselling (as opposed to an emphasis on 'fitness') and this may have helped to increase study retention. Avoiding an emphasis on 'fitness' may have helped to maximise external validity by engaging with, and retaining both those who are and are not already physically active. However,

the current study engaged with a comparatively active sample (potentially due to self-selection), meaning analyses may be less likely to show an effect (due to a ceiling effect). It also limits the application of the findings to a more general, less active, population. The levels of self-reported physical activity were not corroborated by objective activity measurement at baseline (accelerometer) and due to the low numbers and variance in self-reported physical activity, more research is needed to further explore if baseline physical activity influences study attrition.

Failure or success to reduce the amount of cigarettes smoked between baseline and week 8 showed no confidence in predicting drop-out before week 16. This is likely limited by the lack of precision due to the small sample size, as the trend was in favour of those who achieved a reduction in cigarettes smoked before week 16 to demonstrate lower odds of withdrawal, as might be expected.

The present exploratory study had several limitations. Due to the relatively low numbers involved in this pilot trial (and as a result the low number of observations of the outcome of interest), some caution should be used in interpreting the findings due to their imprecision. Nevertheless, we have identified how the findings may influence planning a larger study, and further such analysis should be considered in any future larger study to estimate bias from missing data and study attrition.

The study was also limited in the ethnic diversity of the sample, with 97% reporting being white British, which is typical of the geographical area in which the study was located. This limits the findings to other more ethnically diverse populations and is something that would need to be considered carefully in

future research (as ethnicity is something that has been found to be predictive of dropout in other studies (Leeman et al., 2006)).

We chose not to incentivise data capture to avoid the potential of influencing trial outcomes in this pragmatic study. Preliminary work also revealed that financial incentive was treated with caution by some participants for fear of jeopardising government unemployment benefits. The payment for returning an accelerometer was implemented in an attempt to minimise the loss of expensive equipment and not as an incentive for participation, although it may have acted as such. Incentivisation could be considered for future research in more detail.

3.5. Conclusion

The present research provides important information on factors that may influence attrition within a multi-component smoking reduction study among low socioeconomic status smokers. Retention was at least comparable with the few other studies involving disadvantaged groups with smoking behaviour as a main outcome. These analyses provide unique information on retention in a study aimed at smokers in these groups who did not wish to quit. Only a few factors were quantitatively associated with attrition, suggesting that further research is needed to explain why participants in this type of study drop out.

4. AN EXPLORATORY ANALYSIS OF THE SMOKING AND PHYSICAL ACTIVITY OUTCOMES FROM A PILOT RANDOMISED CONTROLLED TRIAL OF AN EXERCISE ASSISTED REDUCTION TO STOP (EARS) SMOKING INTERVENTION IN DISADVANTAGED GROUPS

A version of this chapter has been published in *Nicotine and Tobacco Research* (Thompson et al., 2015).

4.1. Introduction

Smoking is the biggest contributing factor to health inequalities (Chandola et al., 2004), and although smokers from disadvantaged backgrounds attempt to quit at the same rate as others their success in quitting is lower (Hiscock, Bauld, Amos, Fidler, et al., 2012). This is leading to increasing disparities in smoking prevalence between the upper and lower social grades in the United Kingdom (West, 2008), with similar trends being observed in the United States (Secades-Villa et al., 2013), suggesting a need for interventions specifically designed for these groups (Pyatak et al., 2012).

Good quality evidence for the effectiveness of smoking cessation interventions for disadvantaged groups is limited (Bryant et al., 2011; Ranney et al., 2006) and further research is needed on how best to both increase intervention reach and smoking cessation success (Murray et al., 2009). It is likely that a range of intervention options may be needed to increase reach and to reduce smoking prevalence, such as locating services in community settings with most need, developing roles for outreach workers (e.g., health trainers) (Michie, Rumsey, et al., 2008), and developing multidimensional and complex behaviour change

interventions that are specifically designed for disadvantaged groups (Michie, Jochelson, et al., 2009).

Smoking reduction may be a viable alternative to the traditional abrupt approach to smoking cessation (Lindson-Hawley et al., 2012). In the English Smoking Toolkit Study, 57 percent of current smokers reported they were in the process of cutting down (West, 2008) with a variety of approaches being used (Beard, Vangeli, et al., 2012). Smokers who do not intend to quit in the next month, but cut down with nicotine replacement therapy (NRT), are more likely to make a quit attempt and be abstinent at follow-up (Wang et al., 2008) than those who do not cut down. Smoking reduction may increase the motivation to quit, which is highly predictive of quit attempts, and reduce smoking dependence, which is related to successful quitting (Vangeli et al., 2011). While NRT is popular as an aid for smoking reduction, 31% of smokers believed that sustained use of NRT was 'very' or 'quite' harmful to health (Black et al., 2012) and disadvantaged groups may be sceptical of the effectiveness of NRT in meeting their needs if they were to quit (Wiltshire, Bancroft, Parry, & Amos, 2003). Furthermore, stop smoking advisors and managers have expressed concern that combining NRT with smoking may have negative health consequences (Beard, McDermott, et al., 2012). There is clearly a need for further research on supporting smoking reduction for those who do not wish to use NRT, among both those who do wish to quit and those who don't. Among those who do wish to quit, smoking reduction using pharmacotherapy and behavioural support appears to be as effective as abruptly quitting (Lindson-Hawley et al., 2012).

A review of exercise interventions (versus usual care) as an aid for long-term smoking cessation (Ussher et al., 2012) identified 16 randomised controlled

trials, but all were among smokers who wished to quit, and most were methodologically limited. Of the seven which were adequately powered, three found significant increases in abstinence at the end of treatment, but only one reported increased abstinence rates at 12 month follow up. Variation in study length, type (e.g., structured group-based exercise, physical activity counselling) and the content of the control condition complicated comparison of the studies in the review. The timing of the introduction of physical activity also varied across studies, with some studies promoting involvement in physical activity several weeks before a quit attempt. Almost all studies focused on the use of prescriptive exercise sessions supervised by an exercise professional, with only a few promoting changes in daily lifestyle activity as a way to manage cigarette cravings and withdrawal symptoms.

There is epidemiological evidence to suggest that those who are more physically active are more likely to initiate a quit attempt. A study examining the predicates of smoking relapse amongst smokers completing basic military training in the US Air Force (N=4,303) (Haddock et al., 2000) followed over 1 year revealed that those who made serious quit attempts following basic military training had greater levels of physical activity than those who did not make a quit attempt. This relationship has also been demonstrated in a larger data set of smokers (N=22,659) from the Canadian Community Health Survey (Deruiter et al., 2008) which also found that those smokers who were physically active (n=5,441) were more likely to have made a quit attempt in the past year compared to those who were not physically active (n=17,218). This correlation between higher physical activity levels and initiated quit attempts (although not necessarily causal) raises the possibility that increasing physical activity could facilitate smoking reduction and cessation induction, among those who do not

wish to quit immediately. There are several ways in which an increase in physical activity may putatively facilitate smoking reduction and cessation induction (Taylor & Ussher, 2013) including acutely reducing cravings and withdrawal symptoms (Haasova et al., 2013), a shift away from a smoking identity (Taylor & Ussher, 2013) and reducing weight gain (Aubin, Farley, et al., 2012).

It is usual for smoking cessation intervention trials to use intention to treat (ITT) analyses with an assumption that a participant lost to follow-up is still smoking (West et al., 2005). This assumption is problematic if it is not correct, as it could potentially bias results and statistical tests in favour of an effective treatment if attrition rates are higher in the control group. Also, there is some evidence to suggest that those lost to follow-up may not necessarily be smoking (Borland et al., 2004; Kaper et al., 2005; Nevid & Javier, 1997; Stockton et al., 2000; Twardella & Brenner, 2007). Different approaches to handling missing data on smoking status at follow-up have been suggested, which may provide more reliable estimates of treatment effects (Barnes et al., 2010; Hedeker et al., 2007; Twardella & Brenner, 2008).

The data within this article come from a pragmatic pilot randomised controlled trial (RCT) assessing the feasibility and acceptability of a counselling based intervention designed to support smoking reduction and increases in lifestyle and structured physical activity amongst disadvantaged groups.

We aimed to i) explore the effects of the intervention on smoking and physical activity outcomes at 16 weeks compared with controls based on complete case data among disadvantaged smokers and ii) conduct secondary analyses to

explore both the implications of using different approaches to handling missing data and the effects this has on outcomes.

4.2. Methods

More detailed information on the trial methods and intervention development can be found elsewhere (Taylor et al., 2014).

4.2.1. Participants

Ethical approval for the study was granted by the NHS National Research Ethics Service Committee South West, in the UK (see *Appendix 1*). Recruitment took place in the neighbourhoods of Devonport and Stonehouse (Plymouth) which are among the 3% most deprived areas in the UK (Department of Communities and Local Government, 2011). The sample size calculations (via a scenario analysis), recruitment methods, and baseline characteristics of the sample, have been reported elsewhere (Taylor et al., 2014). In summary, 99 adult moderate to heavy smokers, who wanted to reduce smoking (without NRT) but who reported no plans to quit in the next month, were recruited by either a mailed invitation from their general practitioner or from NHS Stop Smoking Services (SSS), with follow-up telephone calls, or through other community approaches.

4.2.2. Inclusion/exclusion criteria

Participants were eligible to enter the study if they were at least 18 years old, smoked at least 10 cigarettes per day (and had done so for at least two years), reported that they did not want to quit in the next month but did wish to reduce their smoking, were able to engage in moderate intensity physical (walk without stopping for at least 15 minutes, a measure introduced as part of the screening

process which was considered easily applicable within a pragmatic setting and would capture those who are capable of engaging in moderate PA or higher (Kelly et al., 2011)), were registered with a GP, and did not wish to use nicotine replacement therapy (NRT) to reduce smoking. The study focus was on initially reducing smoking, not quitting, so those who expressed an immediate desire to quit were referred directly to the SSS without entering the study. Those wishing to use NRT were excluded to avoid any confounding of the effects of physical activity on their smoking behaviour. We excluded those with severe mental health problems and on-going substance misuse due to the potential difficulties of engaging them in the intervention given the large uncertainties and complexities of its delivery, and the potential to put the safety of researchers at risk. Given the exploratory nature of the study, participants were required to be able to converse in English.

4.2.3. Procedures

After providing informed consent and baseline information, participants were randomised via a web-based randomisation programme (provided by the accredited Peninsula Clinical Trials Unit) to receive either usual care or usual care plus the Exercise Assisted Reduction then Stop EARS intervention. Usual care involved the chance to be referred to their local SSS for specialist support to quit as no support was available for smoking reduction. The Exercise Assisted Reduction then Stop smoking (EARS) intervention consisted of up to 8 weekly client-centred individual motivational support sessions (plus a possible further 4 sessions following a quit attempt), via telephone or in person, to assist with making self-directed changes in smoking and physical activity behaviour, delivered by a team of three Health Trainers (Michie, Rumsey, et al., 2008), plus usual care. The intervention dose was driven by participants on the basis

of need for further support to reduce. Those wishing to make a quit attempt throughout the study period were encouraged to seek the support of specialist stop smoking services. Full details of the intervention can be found in the trial's main report (Taylor et al., 2014). The primary end point was at 16 weeks post baseline for the majority of outcomes, except for data on 4 week post-quit expired air carbon monoxide (CO) confirmed abstinence which was collected at the appropriate time as participants were free to make a quit attempt at any time point in the study.

4.2.4. Measures

Given that the study was a pilot RCT we did not formally assign outcomes to be primary or secondary. At baseline and 16 weeks, data were collected on the number of cigarettes smoked per day (also used to calculate percent reduction at 16 weeks), smoking dependence via the Fagerström test for cigarette dependence (FTCD) (Fagerstrom, 2012; Heatherton et al., 1991), expired air CO (Bedfont Smokerlyser, UK), self-reported physical activity (7 day recall) (Blair, Haskell, et al., 1985), and objectively assessed physical activity via accelerometer (Actigraph GT3X, Pensacola, USA). Quit attempts made and 4 week post-quit expired air CO were recorded accordingly throughout the trial.

4.2.5. Data analyses

For the primary analyses outcomes were compared between groups based on the principle of intention to treat using complete case data. Multivariate logistic and linear regressions were used for binary and continuous outcomes respectively. For secondary analyses, binary smoking outcomes were analysed using multivariate logistic regression based on the assumption that participants lost to follow up were still smoking at baseline values, and by multiple imputation (chained equations); continuous smoking outcomes were analysed

by linear regression based on baseline values carried forward (BCF), last observation carried forward (LOCF), and by multiple imputation chained equations (MICE). Both binary and continuous physical activity outcomes were analysed by linear regression based on baseline values carried forward, last observation carried forward, and by MICE. All analyses were adjusted for baseline age, gender, FTCD score (all variables which are reliably associated with smoking abstinence (Vangeli et al., 2011)), and Health Trainer allocation (as a minimisation factor in randomisation). Imputation models were built for each of the grouped outcomes (binary smoking outcomes, continuous smoking outcomes, binary PA outcomes, and continuous PA outcomes). All analyses were undertaken in Stata (V.12). For examples of Stata commands and output, see *Appendix 3*.

4.3. Results

At 16 weeks, 62% (n=61) of participants provided outcome data, and loss to follow up was similar between treatment groups (Figure 3). Intervention participants attended an average of 4.2 (SD 2.7) of the 8 available support sessions. Detailed information on factors relating to attrition has been reported elsewhere (Thompson et al, under review).

4.3.1. Smoking outcomes

More participants in the intervention arm (35.5%) than in the control arm (9.7%) made a quit attempt at any point in the study (Odd Ratio (OR) 5.05, 95% Confidence Interval (CI): 1.10 to 23.15)), and a greater number of participants in the intervention arm (63.3%) compared with the control arm (32.3%) achieved at least a 50% reduction in smoking at 16 weeks (OR:4.21, CI: 1.32 to 13.39)).

Secondary sensitivity analyses showed that the increased odds of making a quit attempt during the study remained under both assumptions of assumed smoking (OR 4.84, CI: 1.1 to 20.31)) and MICE (OR: 5.51, CI: 1.17 to 25.98)). The increased odds of achieving a reduction of 50% or more in smoking in the intervention arm remained under MICE (OR: 3.48, CI: 1.01 to 12.03)) but not based on the assumption of still smoking. The odds of achieving at least a 25% reduction in expired air CO only showed a difference under MICE (OR: 4.11, 95% CI: 1.43 to 11.87)) in the intervention arm (*Table 15*).

Table 15 Binary smoking outcomes

	Complete Cases			Assumed Smoking (baseline carried forward)			Assumed smoking (last observation carried forward)			MICE*		
	Interventio n (N=30)	Control (N=31)	Odds ratio† (95% CI)	Interventio n (N=49)	Control (N=50)	Odds ratio† (95% CI)	Interventio n (N=49)	Control (N=50)	Odds ratio† (95% CI)	Interventio n (N=49)	Control (N=50)	Odds ratio† (95% CI)
Self-reported quit attempt during study												
Yes (n, (%))	11 (35.5)	3 (9.7)	5.05 (1.10; 23.15)	11 (22.5)	3 (6.0)	4.84 (1.15; 20.31)	N/A	N/A	N/A	16 (32.7)	5 (10.0)	5.51 (1.17; 25.98)
No (n, (%))	20 (63.5)	28 (90.3)		38 (77.6)	47 (94.0)					33 (67.3)	45 (90.0)	
Confirmed quit at 4 weeks post quit-date												
Yes (n, (%))	7 (23.3)	2 (6.5)	4.91 (0.80; 30.24)	7 (14.3)	2 (4.0)	4.33 (0.77; 24.39)	N/A	N/A	N/A	11 (22.4)	4 (8.0)	3.12 (0.60; 16.25)
No (n, (%))	23 (66.7)	29 (93.5)		42 (85.7)	48 (96.0)					38 (75.6)	46 (92.0)	
Reduction of smoking by 50% or more by Week 16												
Yes (n, (%))	19 (63.3)	10 (32.3)	4.21 (1.32; 13.39)	19 (38.8)	10 (20.0)	2.51 (0.98; 6.46)	20 (40.8)	12 (24.0)	2.16 (0.87; 5.37)	30 (57.0)	15 (30.0)	3.48 (1.01; 12.03)
No (n, (%))	11 (36.7)	21 (67.7)		30 (61.2)	40 (80.0)		29 (59.2)	38 (76.0)		19 (43.0)	35 (60.0)	
Expired air CO of ≥25% at week 16												
Yes (n, (%))	17 (56.6)	21 (67.7)	3.17 (0.98; 10.32)	17 (34.7)	10 (20.0)	2.15 (0.81; 5.71)	17 (34.7)	10 (20.0)	2.15 (0.81; 5.71)	28 (57.1)	15 (30)	4.11 (1.43; 11.87)
No (n, (%))	13 (43.4)	10 (32.3)		32 (65.3)	40 (80.0)		32 (65.3)	40 (80.0)				

*MICE: Multiple imputation chained equations

† Adjusted for baseline age, gender, Fagerström Test for Cigarette dependence score, and Health Trainer allocation

CI: confidence interval; CO: carbon monoxide

Primary analyses showed decreases in the adjusted mean difference (95% CI) on the number of self-reported cigarettes smoked per day (-5.14 (-9.09; -1.22)) and FTCD score (-1.56 (-2.68; -0.43)), and a greater percentage reduction in the number of cigarettes smoked (-39.03 (-61.92; -16.15)) in the intervention arm at 16 weeks. Secondary sensitivity analyses supported these differences under all assumptions (BCF, LOCF, and MICE; *Table 16*).

4.3.2. Physical activity outcomes

No differences in the odds of achieving any of the physical activity outcomes were shown in the primary analyses between arms. Secondary analyses showed increased odds of achieving at least 30 minutes of MVPA per day (OR: 2.54, CI: 1.05 to 6.14)) under LOCF, but not through BCF or MICE. Increased odds of achieving at least 150 minutes of MVPA per week in the intervention arm were shown under LOCF (OR: 3.61, CI: 1.48 to 8.81) and BCF (OR: 3.21, CI: 1.33 to 7.77; *Table 17*).

There were no differences in any continuous physical activity outcome, assessed by accelerometer or self-report, in the primary analyses. Secondary analyses showed an increase in the adjusted mean difference (95% CI) for the total minutes of MVPA per week (220.79 (19.61; 421.97)) and per day (31.54 (2.80; 60.28) under LOCF only at 16 weeks (*Table 18*).

Table 16 Continuous smoking outcomes

	Complete Cases			Assumed Smoking (baseline carried forward)			Assumed Smoking (last observation carried forward)			MICE*		
	Intervention (N=30)	Control (N=31)	Difference in means† (95% CI)	Intervention (N=49)	Control (N=50)	Difference in means† (95% CI)	Intervention (N=49)	Control (N=50)	Difference in means† (95% CI)	Intervention (N=49)	Control (N=50)	Difference in means† (95% CI)
Self-reported cigarettes per day (mean (SD))	9.06 (8.09)	13.59 (7.51)	-5.15 (-9.09; -1.22)	12.66 (9.69)	17.59 (14.01)	-4.60 (-9.25; -0.10)	11.78 (8.54)	15.42 (7.35)	-3.43 (-6.46; -0.40)	9.25 (1.42)	14.10 (1.32)	-4.78 (-8.67; -0.91)
CO (ppm) (mean (SD)), n	12.3 (8.31)	15.77 (7.83)	-3.04 (-7.18; 1.10)	15.33 (8.70), 49	16.92 (8.57), 49	-1.33 (-4.65; 1.99)	15.51 (8.85), 49	16.64 (8.43), 50	-0.96 (-4.26; 2.33)	13.13 (1.35)	16.38 (1.46)	-3.16 (-6.92; 0.60)
Amount reduced (%) (mean (SD))	-59.70 (32.54)	-20.13 (50.10)	-39.03 (-61.92; -16.15)	-36.55 (38.78)	-12.48 (40.42)	-23.08 (-38.87; -7.28)	-38.45 (40.31)	-16.70 (41.51)	-20.94 (-37.40; -4.47)	-55.96 (6.44)	20.74 (8.85)	-33.49 (-56.57; -10.41)
FTCD (mean (SD)), n	3.09 (2.20), 22	4.21 (2.50), 29	-1.56 (-2.68; -0.43)	4.27 (2.22)	5.06 (2.51)	-0.70 (-1.38; -0.02)	5.02 (2.51)	4.04 (2.28)	-0.89 (-1.57; -0.21)	2.67 (0.39)	4.19 (0.50)	-1.57 (-2.72; -0.42)

*MICE: Multiple imputation chained equations

† Adjusted for baseline age, gender, Fagerström Test for Cigarette dependence score, and Health Trainer allocation

CI: confidence interval; CO: carbon monoxide; FTCD: Fagerström Test for Cigarette Dependence; ppm: parts per million; SD: standard deviation

Table 17 Binary physical activity outcomes

	Complete Cases			Baseline carried forward			Last observation carried forward			MICE*		
	Intervent ion (N=30)	Control (N=31)	Odds ratio† (95% CI)	Intervent ion (N=49)	Control (N=50)	Odds ratio† (95% CI)	Intervent ion (N=49)	Control (N=50)	Odds ratio† (95% CI)	Intervent ion (N=49)	Control (N=50)	Odds ratio† (95% CI)
Self-report 30 mins MVPA per day												
Yes (n, (%))	17 (56.7)	16 (51.6)	1.31 (0.43; 3.94)	31 (63.3)	23 (46.0)	2.20 (0.93; 5.22)	31 (63.3)	22 (44.0)	2.54 (1.05; 6.14)	26 (53.1)	21 (42.0)	1.37 (0.47; 4.05)
No (n, (%))	13 (43.3)	15 (48.4)		18 (36.7)	27 (54.0)		18 (36.7)	28 (56.0)		23 (46.9)	29 (58.0)	
Self-report >150mins MVPA per week												
Yes (n, (%))	21 (70.0)	16 (51.6)	2.70 (0.85; 8.58)	35 (71.4)	23 (46.0)	3.21 (1.33; 7.77)	36 (73.5)	23 (46.0)	3.61 (1.48; 8.81)	33 (67.3)	21 (42.0)	3.36 (1.14; 9.93)
No (n, (%))	9 (30.0)	15 (48.4)		14 (28.6)	27 (54.0)		13 (26.5)	27 (54.0)		16 (32.7)	29 (58.0)	
Accelerometer 30 mins MVPA per day	(N=21)	(N=18)		(N=36)	(N=33)		(N=37)	(N=35)				
Yes (n, (%))	8 (38.1)	6 (33.3)	1.18 (0.24; 5.68)	18 (50.0)	15 (45.5)	1.52 (0.53; 4.34)	18 (48.6)	15 (42.9)	1.58 (0.57; 4.36)	19 (38.8)	18 (36.0)	1.25 (0.38; 4.11)
No (n, (%))	13 (61.9)	12 (66.7)		18 (50.0)	18 (54.5)		19 (51.4)	20 (57.1)		30 (61.2)	32 (64.0)	

*MICE: Multiple imputation chained equations

† Adjusted for baseline age, gender, Fagerström Test for Cigarette dependence score, and Health Trainer allocation

CI: confidence interval; MVPA: moderate and vigorous physical activity

Table 18 Continuous physical activity outcomes

	Complete Cases			Baseline carried forward			Last observation carried forward			MICE*		
	Intervention (N=30)	Control (N=31)	Difference in means† (95% CI)	Intervention (N=49)	Control (N=50)	Difference in means† (95% CI)	Intervention (N=49)	Control (N=50)	Difference in means† (95% CI)	Intervention (N=49)	Control (N=50)	Difference in means† (95% CI)
Total minutes MVPA per week (mean (SD))	400.00 (559.56)	378.55 (514.22)	23.53 (-261.72; 08.78)	490.61 (596.11)	309.52 (444.31)	185.29 (-17.89; 388.47)	509.49 (598.41)	297.52 (439.42)	220.79 (19.61; 421.97)	435.92 (576.35)	349.85 (488.08)	92.43 (-188.10; 372.96)
Total minutes MVPA per day (mean (SD))	57.14 (79.94)	54.08 (73.89)	3.36 (-37.39; 44.11)	70.09 (85.16)	44.22 (63.47)	26.47 (-2.56; 55.50)	72.78 (85.49)	42.50 (62.77)	31.54 (2.80; 60.28)	62.27 (82.34)	49.98 (69.73)	13.20 (-26.87; 53.30)
Accelerometer total minutes MVPA per day (mean (SD), n)	27.34 (21.03), 21	26.22 (19.03), 18	0.44 (-14.40; 15.28)	30.60 (21.22), 33	30.79 (25.10), 36	1.95 (-8.76; 12.65)	31.60 (22.18), 37	28.66 (22.80), 35	5.36 (-4.49; 15.20)	26.65 (20.17), 49	25.29 (18.89), 50	1.34 (-10.81; 13.50)

*MICE: Multiple imputation chained equations

† Adjusted for baseline age, gender, Fagerström Test for Cigarette dependence score, and Health Trainer allocation

CI: confidence interval; MVPA: moderate and vigorous physical activity; SD: standard deviation

4.4. Discussion

This article presents data from a trial of a smoking reduction intervention with a focus on physical activity among disadvantaged smokers who did not want to initially quit. We believe our study is the first of its kind to give insight into the likely cessation induction rates for those entering a trial who do not want to quit but then do make a quit attempt as a result of smoking reduction, and illustrates potential variation in findings resulting from differing intention-to-treat assumptions. Whilst the findings were encouraging, the study was exploratory with no a priori sample size estimation. Caution is needed in interpreting the results due to the relatively small sample size and potential lack of statistical power.

Individuals in the intervention arm made a greater number of quit attempts when compared with those in usual care, suggesting that an intervention designed to support reduction could potentially lead to an increase in cessation attempts among those who initially had no desire to quit. The trend for greater success in the intervention compared with usual care for those achieving a 4 week post-quit CO confirmed quit was promising. Along with positive effects of the intervention on reported smoking dependence and the amount of cigarettes smoked per day, it would seem that the intervention may impact on a variety of smoking outcomes among disadvantaged smokers.

Secondary analyses showed that the assumption that those lost to follow up were still smoking was potentially conservative when compared with the primary complete case analysis or MICE. Despite the conservative nature of this assumption, the assumption that loss to follow up meant participants were still smoking only contradicted one finding from the primary analyses (i.e., those

achieving a reduction of greater than 50% at week 16). It thus appears that this assumption has the potential to under-estimate the beneficial effects of the intervention (Barnes et al., 2010; Hedeker et al., 2007; Twardella & Brenner, 2008), and although this approach has been widely advocated, more research into dealing with missing data in smoking trials is justified.

Our intervention failed to demonstrate any positive effects on physical activity behaviour at 16 weeks. Secondary analyses showed increased odds of those in the intervention completing 30 minutes of MVPA per day or 150 minutes of MVPA per week compared with usual care at 16 weeks. It is likely that the study was underpowered to detect changes in PA using only complete case data, but there is some support for increases in PA using imputation. Complete case analyses were conservative compared with the three approaches to imputation for missing physical activity data, where MICE showed 11% more people in the intervention completing 30 minutes of MVPA per day, BCF 17% more, and LOCF 19% more compared with only 5% more with complete cases. Similar differences were shown for the number of those completing at least 150 minutes of MVPA per week, suggesting using only complete case analysis for physical activity data may lead to an underestimation of intervention effects. Other research comparing the effects of imputation and modelling methods in the analysis of physical activity trial data with missing outcomes reports wide variation in the estimates of mean change over time and intervention effects when applying *ad hoc* methods such as BCF and LOCF (Wood, White, Hillsdon, & Carpenter, 2005), and similar results were found here. As suggested elsewhere (Wood et al., 2005) *ad hoc* imputation methods vary widely in their assumptions about the missing data, and more advanced imputation techniques such as multiple imputation should be employed where possible. In the present

case, it is possible that the intervention's primary focus on smoking reduction meant that increasing physical activity was not as well addressed, particularly in regard to longer term maintenance and more support is needed to sustain increased PA levels. Disadvantaged groups undertake less leisure-time physical activity but undertake more activity associated with work and active transport (in part due to low car ownership) (Cerin et al., 2009; Cerin & Leslie, 2008). This relationship clouds an understanding of the effectiveness of interventions to generally increase physical activity (Cleland et al., 2012). Despite minimising the focus on doing structured exercise rather than lifestyle physical activity in our participant recruitment materials we may have recruited more active smokers resulting in a potential ceiling effect when trying to increase physical activity in the intervention.

4.5. Conclusion

This study presents encouraging findings from a pilot pragmatic randomised controlled trial and adds to the limited literature on the role of physical activity for smoking reduction, rather than abrupt quitting. A fully powered trial to test the effectiveness of a counselling-based intervention with a focus on physical activity and smoking reduction among disadvantaged groups is now needed. Such a trial should examine the mediating role of changes in physical activity on smoking reduction as well as qualitatively explore how physical activity can help in self-regulation of smoking.

5. INTERVENTION DELIVERY FIDELITY ASSESSMENT OF A MOTIVATIONAL INTERVIEWING BASED COUNSELLING INTERVENTION FOR MULTIPLE BEHAVIOURS

5.1 Background

Complex interventions consist of multiple interacting components and are recognised as having varied challenges in their design, implementation and evaluation and it has been highlighted that intervention fidelity is under evaluated (Craig et al., 2008). Intervention fidelity (or treatment fidelity) refers to methodological strategies used to assess and enhance the reliability and validity of complex behavioural interventions, in order to increase the confidence that changes in the dependent variable are attributable to the independent variable (Borrelli et al., 2005). It also helps to determine that manipulation of the independent variable occurred as planned (Moncher & Prinz, 1991). Intervention fidelity acts as a potential moderator of the relationships between interventions and their intended outcomes (which is one of the key reasons it should be assessed) (Carroll et al., 2007). Assessment of treatment fidelity helps to explain study findings, plan for future improvements to interventions, and potentially increase statistical power and effect size by minimising random and unintended effects (Moncher & Prinz, 1991). Enhancing treatment fidelity improves both internal and external validity as a high degree of treatment fidelity is needed both for study replication and for generalisation of treatments to applied settings (Borrelli et al., 2005). Without evaluating treatment fidelity in a new intervention, significant results can not necessarily be attributed to the treatment as there may be unknown factors that may have been included or excluded as part of the treatment. Additionally, nonsignificant

results may result from a lack of treatment fidelity as opposed to an ineffective treatment (Bellg et al., 2004; Moncher & Prinz, 1991), a phenomenon known as a 'type III' error (Dobson & Cook, 1980; Schinckus, Van den Broucke, & Housiaux, 2014). Insufficient assessment of treatment fidelity may therefore result in the rejection of effective interventions, and the adoption of ineffective interventions in clinical and public health settings at a high cost to patients, providers and organisations (Bellg et al., 2004; Borrelli, 2011; Henggeler, Melton, Brondino, Scherer, & Hanley, 1997; Moncher & Prinz, 1991).

A comprehensive treatment fidelity framework for tailored health behaviour interventions exists, covering five domains: Study Design, Provider Training, Treatment Delivery, Treatment Receipt, and Treatment Enactment (Bellg et al., 2004; Borrelli et al., 2005). Of relevance to this paper, is the third domain of treatment delivery, where low quality practice could be compared to a partial dose of an experimental drug. The fidelity of the delivery of behavioural treatments has historically been insufficiently considered (Miller & Rollnick, 2014) and as such its assessment is vital in improving confidence in treatment effects and the active processes that produce high quality interventions. The gold standard for assessing whether interventions are delivered as specified is recognised as the use of audio or videotapes for objective verification of delivery, evaluated against criteria developed a priori (Borrelli, 2011).

Assessing fidelity of delivery has two main purposes: a) for use in supervision to improve provider skills and delivery, and b) for use in analytical models to determine the relationship between fidelity of delivery and outcomes (Borrelli, 2011). The context of this research examines the methods behind assessing the delivery fidelity of a novel pilot intervention of multiple behaviour change,

and provides information and evaluation of the methods used in order to make recommendations for future research, with the identification of areas which may be improved by addressing training relating to the areas identified as having lower fidelity for delivery. Historically, health behaviours have been addressed individually and there are mixed views on whether multiple behaviour changes (e.g., increases in physical activity and dietary change) should be tackled simultaneously or sequentially when smokers quit (McEwen et al., 2006). By attempting to assess delivery fidelity as part of a novel multiple behaviour change intervention, it will help to highlight the difficulties practitioners may face when attempting to deliver an intervention addressing more than one health behaviour simultaneously. This has the potential to reveal areas where the theorised integration of behaviours is not being successfully delivered, and highlight areas which require future development in terms of provider training and intervention delivery.

5.2 Methods

This section begins with a detailed background of the EARS intervention in order to provide sufficient context for understanding the elements which are assessed as part of the delivery fidelity assessment.

5.2.1 EARS intervention structure and delivery

The EARS intervention was designed to involve up to eight weeks of one to one support from a HT, in person or by phone, after an initial face-to-face session. The HT provided no supervised physical activity sessions but offered subsidised access to physical activity opportunities (e.g. swimming, gym admission, and

transport subsidies to walking events) subject to individual preference. The focus was always on making any change in physical activity sustainable through motivational support.

Participants were given up to eight weeks to cut down until they were ready to make a quit attempt. To count as abstinent a participant needed to have set a quit date within 12 weeks of randomisation to provide confirmation of a successful 4-week cessation by the final assessment at 16 weeks within the pilot RCT. Anyone who was ready to set a quit date was encouraged to attend and referred to the local SSS for support if they wished to get support. After quitting they were also offered weekly counselling to support on-going physical activity from the HT for up to a further six weeks.

5.2.2 EARS intervention principles and theoretical basis

The intervention was client-centred in that smokers (who want to reduce but not quit in the immediate future) set the speed of reduction and their level of engagement in physical activity. The HT worked with the participant using client-centred motivational interviewing (MI) techniques (Miller, 1983) throughout the intervention. The intervention was further informed by Self-Determination Theory (SDT) (Deci & Ryan, R. M., 1985; Deci & Ryan, 2000) which suggests that changing smoking behaviour will be facilitated by helping the smoker to fulfil three core human needs: a sense of competence or mastery, autonomy or control, and relatedness or companionship. Enhancing autonomy and competence motivations has been shown in prior research to increase abstinence rates and lead to greater cessation (Williams et al., 2006). Links between MI and SDT have been made in the literature (Markland, Ryan, Tobin, & Rollnick, 2005; Miller & Rollnick, 2012; Patrick & Williams, 2012;

Vansteenkiste & Sheldon, 2006), suggesting that there may be good synergies in combining these two intervention approaches: both focus on helping the client to develop a sense of ownership of any change and empowerment. In addiction research, there is evidence that a client-centred counselling approach is effective for engaging with clients, building commitment to change (Boardman, Catley, Grobe, Little, & Ahluwalia, 2006), and increasing cognitive dissonance (Draycott & Dabbs, 1998) which can predict treatment outcomes (Moyers et al., 2007). Reviews suggest that MI is effective in treating substance abuse (Smedslund et al., 2011) and for smoking cessation (Heckman, Egleston, & Hofmann, 2010; Hettema & Hendricks, 2010; Lai, Cahill, Qin, & Tang, 2010). MI has also been shown to be an effective intervention for increasing physical activity (Hardcastle, Taylor, Bailey, & Castle, 2008). The EARS intervention drew from principles of MI but also drew on SDT and other theories of behaviour change (as below).

In particular, MI does not focus on social influences on behaviour change, but SDT-founded interventions seek to help clients fulfil a need for a sense of relatedness. In the EARS intervention, techniques are described that were used to help participants to find social support for smoking reduction and increasing physical activity.

The EARS intervention was also informed by Social Cognitive Theory (Bandura, 1986) and Control Theory (Carver & Scheier, 1982), in that it sought to promote self-regulation by helping clients to build confidence over time to reduce smoking and increase physical activity. The self-regulation processes we specifically targeted were action-planning self-monitoring, review of progress, problem-solving and review of goals – together these represent a process of

experiential learning. Uniquely, this intervention also sought to help participants to use physical activity to self-regulate smoking by identifying situations where it may be possible to reduce withdrawal symptoms and desire to smoke, enhance positive mood, and break the link between environment and smoking behaviours. A range of behaviour change techniques were matched to the above theoretical processes of change (see *Table 19*) and these were all included in the EARS training programme.

Finally, EARS also drew from research on stage matched interventions (Everson-Hock et al., 2010; J O Prochaska & DiClemente, 1983) to help focus the use of specific behavioural change techniques at the appropriate time. Following an assessment of readiness to change and perceived importance of and confidence about cutting down, intervention techniques were used, as needed, to shift participants from pre-contemplation, contemplation and planning stages to action and maintenance, in terms of smoking reduction and quitting, and increasing physical activity as a way to facilitate changes in smoking behaviour. These additional elements specific to the EARS intervention were added to skills and competencies based on the NHS Health Trainer Handbook (Michie, Rumsey, et al., 2008).

Table 19 Processes targeted (objectives) and related content for the EARS intervention

Intervention process /objective	Intervention strategy	Behaviour Change Techniques (See Table 20 for description)	Theoretical Domains
<p>1. Active participant involvement.</p> <p>Develop rapport, building trust, and shared respect and empower the participant to be the primary agent of change.</p>	<p>Use MI principles and communication skills. Exhibit empathy using Open questions, Affirmation. Reflections, Summaries (OARS).</p> <p>Individual tailoring of techniques and responses to the individual participant's existing knowledge, skills, needs or preferences.</p>	<p>RC1, RC2, RC4, RC7, RC8, RC9, RC10</p> <p>RD1, RD2</p>	<p>Knowledge; Skills; Identity (e.g. social identity); Capability beliefs; Beliefs about consequences; Reinforcement; Intentions; Goals; Memory or attention; Context /resources; Social influences; Emotion; Behavioural regulation.</p>

Intervention process /objective	Intervention strategy	Behaviour Change Techniques (See Table 20 for description)	Theoretical Domains
<p>2. Explore initial beliefs about <i>cutting down</i> (importance and confidence, triggers for smoking).</p> <p>Build /enhance motivation and confidence for <i>cutting down</i>.</p> <p>Desire to quit may also be discussed.</p>	<p>Use OARS (as above) to explore current and past smoking behaviour, the pros and cons of cutting down. 0-10 questions to explore importance and confidence. Use OARS to develop discrepancies (e.g. by exploring possible futures).</p> <p>Identify strengths and barriers (e.g. by exploring past experiences of success and failure or asking 'what might stop you?'). Identify possible solutions to barriers.</p> <p>Exchange information on pros and cons of cutting down and barrier-solutions using the elicit-provide-elicite (Ask-Tell-Discuss) technique.</p>	<p>RI1, RI2, BM3, BM9</p> <p>RC6, RI3, RI4, A2, BM2, BS2</p> <p>RC2, A2, BM2, BS2</p>	<p>Knowledge; Capability beliefs; Beliefs about consequences; Intentions; Context /resources; Social influences; Emotion</p>

Intervention process /objective	Intervention strategy	Behaviour Change Techniques (See Table 20 for description)	Theoretical Domains
<p>3. Explore initial beliefs about <i>Physical Activity</i> and using it as an aid to cutting down (importance and confidence, barriers to PA).</p> <p>Build /enhance motivation and confidence for <i>Physical Activity</i>.</p>	<p>Use OARS (as above) to explore pros and cons. Decisional balance tool, 0-10 questions to explore importance and confidence about introducing additional physical activities. Use OARS to develop discrepancies.</p> <p>Identify strengths and barriers (e.g. by exploring past experiences of success and failure or asking 'what might stop you?'). Identify possible solutions to barriers.</p> <p>Exchange information on pros and cons of PA and on barriers /solutions using the elicit-provide-elicite (Ask-Tell-Discuss) technique.</p>	<p>C37</p> <p>C18, C37</p> <p>C8, C31, C37</p>	<p>Knowledge; Capability beliefs; Beliefs about consequences; Intentions; Context /resources; Social influences; Emotion</p>
<p>4. Set goals and discuss strategies <i>to reduce smoking</i>.</p>	<p>Set SMART goals with smoker to reduce smoking. Discuss /offer a choice of specific strategies. Negotiate strategy and rate of smoking reduction (over following 1 and 4 weeks).</p> <p>Encourage self-monitoring of daily smoking.</p>	<p>BS3, BS4, BS6, BS7, BS8, BS9</p> <p>C12, C23</p> <p>BS6</p>	<p>Intentions; Goals; Behavioural regulation.</p>

Intervention process /objective	Intervention strategy	Behaviour Change Techniques (See Table 20 for description)	Theoretical Domains
5. Set goals and discuss strategies <i>for Physical Activity</i>	<p>Set SMART goals with smoker to increase PA /introduce new physical activities. Discuss preferences and smoker to choose activities. Signpost to relevant PA/exercise opportunities.</p> <p>Encourage self-monitoring of daily or weekly physical activity (e.g. using a pedometer).</p>	<p>C5, C7, C9, C23, C26, C24</p> <p>C16</p>	Intentions; Goals; Behavioural regulation; Context /resources
6. Review and reflect on efforts <i>to cut down smoking</i> to build confidence gradually and perceptions of control and ability to self-regulate.	<p>Smoker and HT review progress with smoking reduction. Any successes are reflected on and reinforced.</p> <p>Smoker and HT discuss any setbacks (reframing to normalise them, identifying social, environmental or other barriers and exploring ways to overcome them).</p> <p>Set new targets (perhaps to quit).</p> <p>Reflection on /reinforcement of the smoker's skills in avoiding or managing relapse.</p> <p>Re-assessment /checking of motivation /perceived benefits of reducing smoking and also of making an attempt to quit.</p>	<p>RC7, RC8, BM3, BS5</p> <p>A2, R14, RC6, BS1, BM5, BS8</p> <p>BS3, BS4, BS5, BS6, BS7, BS9</p> <p>BM2, BM3</p> <p>BM2, BM9</p>	Skills; Identity (e.g. social identity); Capability beliefs; Beliefs about consequences; Memory or attention; Context /resources; Social influences; Emotion; Behavioural regulation

Intervention process /objective	Intervention strategy	Behaviour Change Techniques (See Table 20 for description)	Theoretical Domains
<p>7. Review and reflect on efforts <i>to increase Physical Activity</i> to build confidence gradually and perceptions of control and ability to self-regulate.</p>	<p>Smoker and HT review and reflect on successes in increasing PA /introducing new physical activities.</p> <p>Smoker and HT discuss any setbacks (reframing to normalise them, identifying social, environmental or other barriers and exploring ways to overcome them).</p> <p>Set new targets for PA.</p> <p>Re-assessment /checking of motivation /perceived benefits of physical activity in relation to smoking reduction, but also discussing other personal benefits.</p>	<p>C11</p> <p>C8, C28, C29, C35</p> <p>C10, C6, C7, C16</p> <p>C37, C15</p>	<p>Skills; Identity (e.g. social identity); Capability beliefs; Beliefs about consequences; Memory or attention; Context /resources; Social influences; Emotion; Behavioural regulation</p>

Intervention process /objective	Intervention strategy	Behaviour Change Techniques (See Table 20 for description)	Theoretical Domains
8. Integration of concepts: Building an association between PA and smoking reduction.	The HT introduces PA as a healthy behaviour and aid to cutting down and quitting. A clear rationale is presented for how PA might be relevant to reducing smoking (as a distraction, as a way to reduce withdrawal symptoms such as stress or cravings). The HT and smoker agree to experiment with using PA. The smoker reflects on use of PA and relates it to smoking urges and /or to number of cigarettes smoked.	RD1, RC2, RC8, R6 C6, C11	Beliefs about consequences; Emotion
9 and 10. Engage social support to facilitate behaviour change (both for reducing smoking and for physical activity)	Exploring the possible role of social influences as potential barriers to change and as potential facilitators of change is encouraged during the motivation, action-planning and review stages above. Social support is conceptualised as being either informational (e.g. helping to make plans) practical (e.g. providing transport), or emotional (e.g. encouraging)	A2 C29	Social Influences; Emotion

Intervention process /objective	Intervention strategy	Behaviour Change Techniques (See Table 20 for description)	Theoretical Domains
11. Identify and reinforce any identity shifts towards being a more 'healthy person' or 'healthy living'. This represents a generalisation of the specific desire to stop smoking or to be more active into a more general self-concept of being someone who is healthy.	Recognise and reinforce any identity change talk using reflective listening techniques.	RC2, RC7, RC8, C30 NB: Explicitly encouraging /reinforcing positive changes in social identity is not currently a recognised BCT	Identity (e.g. social identity); Emotion
12. Referral to NHS Stop Smoking Services if needed.	Ask if ready to quit and refer to NHS SSS if desired	RC2, RD1	Context /resources

BCT: Behaviour change technique; HT: Health Trainer; NHS: National Health Service; PA: Physical Activity; SMART: Specific, Measurable, Achievable, Realistic, Time bound; SSS: Stop Smoking Services

5.2.3 Behavioural targets and support for action planning

The study inclusion/exclusion criteria meant that we could assume that smokers were ready to cut down but not quit in the next month. Given the addictive nature of smoking behaviour, part of the challenge of reducing smoking was deciding what to do and specifically how to do it. Having a clear and consciously regulated plan was considered to be helpful in disrupting habitual, automated patterns of smoking behaviour, and for extinguishing cigarette cravings associated with conditioned cues and environments (Conklin, 2006; Orbell & Verplanken, 2010). Initial pilot work, prior to the trial, highlighted that no two smokers had identical personal situations or smoking and physical activity experiences, and that any intervention would require flexibility and tailoring to individual needs.

We therefore created a set of materials to help participants to think about and discuss different possible strategies for cutting down. Participants were encouraged to set an initial smoking reduction goal of 50% during the first four weeks, using one of four different reduction strategies (Lindson et al., 2009) as follows:

1. *Hierarchical Reduction*: This involves identifying the easiest to the hardest cigarettes to give up during the course of a typical day, and then systematically giving up either the easiest or hardest cigarettes over time until a goal is reached;
2. *Smoke Free Periods*: This involves identifying blocks of time through the day where the participant will not smoke, progressively increasing the length of these periods over time;

3. *Scheduled Reduction*: This involves spacing cigarettes evenly through the day (e.g. smoking every 30 minutes) and progressively increasing the time between each cigarette;
4. *Planned Reduction*: This involves setting a target of a maximum number of cigarettes to smoke per day, and progressively decreasing this number over time.

The strategy chosen was not fixed but was used by participants in an exploratory way to discover which was most suitable. HTs recorded any reduction plans and used these to review and update further goals in subsequent sessions with participants as a way of encouraging self-monitoring and self-regulation. For each strategy, the aims were to build participants' confidence to reduce smoking, allow choice in how they achieve this and to encourage participants to seek support from others as appropriate.

5.2.4 Increasing physical activity

In the initial session HTs initiated a dialogue about how physical activity may influence smoking, and may help any reduction. This was expected to include reduction of cravings (Haasova et al., 2013), stress reduction and using physical activity as a distraction. Pilot work suggested that it was easier for the HT to focus on smoking reduction initially, and then introduce and develop goals for physical activity as a facilitating behaviour, though this was open for negotiation with the participant. As we did not exclude people who were already physically active, we expected participants to vary greatly in the amount of physical activity they were already doing and hence the intervention needed to be responsive to this variation.

The initial aim was to increase motivation and confidence to increase physical activity and to build beliefs in the reinforcing value of physical activity to aid smoking reduction. Later in the sessions, physical activity facilitation focused mainly on encouraging the selection of options that were likely to be sustainable and accessible for the individual participant. The focus was on moderate intensity lifestyle activity (including walking, active transport, or activities with few barriers to engagement) and activities that were enjoyable to the participant. The HT had a number of options to help participants increase physical activity including: a free low-cost MP3 player preloaded with a ten minute spoken isometric exercise instruction track (Ussher, Cropley, Playle, Mohidin, & West, 2009); a free rubber exercise band for home use; a free pedometer (self-monitoring with pedometers has been shown to increase physical activity (Bravata et al., 2007)); and free or subsidised access to local leisure and exercise facilities (e.g. for swimming or gym use). Participants were encouraged to self-monitor the number of daily steps they achieved and set goals (both important behaviour change techniques (Michie, Abraham, Whittington, McAteer, & Gupta, 2009)) and identify their use of PA in managing smoking cravings (or providing a distraction) and elicit any other positive associations that they recognised. The focus was not only on increasing the volume of physical activity and using this as an aid to reduce smoking, but also to help participants build a more generalised sense of competence, control and companionship through the activities they engaged in.

5.2.5 Training the Health Trainers

We first went through routine HT training (Michie, Rumsey, et al., 2008) to ensure the HTs had a basic level of understanding of behaviour change techniques, followed by training based on an EARS HT manual (see *Appendix*

4), covering physical activity counselling to achieve the above aims. *Table 20* shows a list of behaviour change techniques (BCTs) (Michie, Hyder, Walia, & West, 2011; Michie, Ashford, et al., 2011) that the HTs were trained to use and are linked to the main theoretical constructs (see *Table 19*) that underpinned the intervention.

Table 20 Planned behaviour change techniques to be used in intervention sessions
(authors' alterations to original text in *italics*)

Behaviour addressed	BCT (modified for the EARS protocol of delivery)
Smoking Reduction (Michie, Hyder, et al., 2011) ^a	BM2 (boost motivation and self-efficacy)
	BM3 (<i>offer</i> feedback on current behaviour)
	BM5 (<i>offer</i> normative information about others' behaviour and experiences)
	BM9 (<i>elicit</i> reasons for wanting and not wanting to stop smoking or cut down)
	BM11 (measure CO)
	BS1 (facilitate barrier identification and problem solving)
	BS2 (facilitate relapse prevention and coping)
	BS3 (facilitate action planning/develop treatment plan)
	BS4 (facilitate goal setting)
	BS5 (prompt review of goals)
	BS6 (prompt self-recording)
	BS7 (<i>offer to provide support with techniques</i> for changing behaviour)
	BS8 (<i>prompt thoughts</i> on environmental restructuring)
	BS9 (<i>help</i> set graded tasks)
	A2 (advise on/facilitate use of social support)
	RD1 (tailor interventions appropriately)
	RD2 (emphasise choice)
	RI1 (assess current and past smoking behaviour)
	RI2 (assess current readiness and ability to quit-cut down)
	RI3 (assess past history of quit attempts)
	RI4 (assess withdrawal symptoms)
	RC1 (build general rapport)
	RC2 (elicit and answer questions)

	RC4 (explain expectations regarding treatment programme)
	RC6 (provide information <i>where appropriate</i> on withdrawal symptoms)
	RC7 (use reflective listening)
	RC8 (elicit client views)
	RC9 (summarise information/confirm client decisions)
	RC10 (provide reassurance)
Physical Activity (Michie, Ashford, et al., 2011) ^b	C5 (goal setting – behaviour)
	C6 (goal setting – to achieve possible benefits from increasing physical activity)
	C7 (action planning)
	C8 (barrier identification/problem solving)
	C9 (set graded tasks)
	C10 (prompt review of behavioural goals)
	C11 (prompt review of achievement of benefits from PA)
	C12 (prompt rewards contingent on progress)
	C15 (prompting generalisation of a target behaviour)
	C16 (prompt self-monitoring of behaviour)
	C18 (prompting focus on past success)
	C23 (teach to use prompts/cues)
	C24 (environmental restructuring)
	C26 (prompt practice)
	C28 (facilitate social comparison)
	C29 (plan social support)
	C30 (prompt identification as role model)
	C31 (prompt anticipated regret from not changing current behaviour)
	C35 (relapse prevention/coping planning)
	C37 (motivational interviewing)

Note: The BCTs are utilised in a highly responsive and tailored manner to the individuals' needs and rate of change across sessions.

^aSpecific focus on behaviour and addressing motivation (BM), specific focus on behaviour and maximising self-regulatory capacity/skills (BS), promote adjuvant activities (A), general aspects of the interaction focusing on the delivery of the intervention (RD), general aspects of the interaction focusing on information gathering (RI), general aspects of the interaction focusing on general communication (RC).

^bLettered coding added here to aid identification in *Table 19*.

5.2.6 Design

The intended intervention processes summarised in *Table 19* were used as a basis for generating items for a checklist to assess intervention delivery and fidelity. Following a brief scoring-standardisation procedure, the checklist was applied to a purposive selection of consultation recordings and descriptive analyses were used to summarise the data.

5.2.7 Sampling frame

All consultation sessions were audio-recorded subject to informed consent. Consent for this was taken on the main study consent form and this was checked verbally prior to starting the first consultation. A sample of three sessions for 30 participants split between the three HTs (90 audio recorded and transcribed sessions in total) was selected to provide examples from early, late and in the middle of the study period (to smooth out any HT practice effects). For each client, three (out of a possible eight) consultations were selected for coding to provide examples of intervention techniques from early-stage motivation through to later stage progress-reviewing/relapse prevention.

5.2.8 Measures and procedure

To assess intervention fidelity (and at the same time quantify delivery in terms of predefined manualised elements), we used the Dreyfus system for assessing skill acquisition (Dreyfus, 1989), see *Figure 4*, to score recorded consultations with respect to the HT's skill in delivering each of the twelve intervention processes (*Table 19*). A scoring checklist and instructions were developed and these are provided in *Appendix 5*. The checklist was applied initially by three researchers with expertise in behaviour change (Adrian Taylor, Tom Thompson, and Colin Greaves) to a sample of six consultations from two participants.

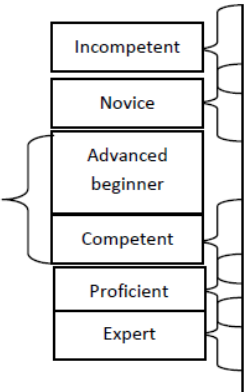
Scores were compared and reasons for any discrepancies were discussed to produce a consensus about how to apply the scoring system. A similar procedure was adopted at a later stage between TT and another researcher (Jeff Lambert) to expand the number of sessions scored for fidelity.

In total, between three researchers (TT, CGVS, JDL) consultation data from 30 participants across the three HTs (using three consultations per participant) were scored to produce an overall intervention fidelity rating for each item and for each HT (see *Table 21*). This was done by listening to the set of (3) recorded consultations for each participant and reading the transcripts of the same consultations, then rating the fidelity for each item on the checklist. Because of limitations in time and resources, we did not conduct formal inter-rater reliability checks; this would have required all researchers to rate fidelity for around 20-30 participants each. However, we did split the coding for each HT between the three researchers, so that each researcher coded at least two participants for each HT. The average score for the HT is therefore the average of the scores given by three coders.

Due to the clear descriptions associated with each score (see checklist scoring instructions in *Appendix 5*) and the steps taken to establish a consensus between coders on the approach to scoring, interpretation of scores is relatively straightforward: Scores of 0 or 1 represented poor delivery (or no delivery) of the intended process. A score of 3 or more was considered to represent a reasonable quality of intervention delivery. Scores of 5 or 6 represented very high (expert level) quality, which we were not expecting to see very often with our trainers delivering this novel intervention for the first time. It was accepted that for item 9 (seeking to identify and reinforce shifts in identity), the

opportunities to deliver this process would be scarce and so a lower score (1.5 or more) was considered acceptable for this item. Item 12 (referral to smoking cessation services) was scored as either 0 or 1 (yes or no) and so is not reported in *Table 21*.

Figure 4 The Dreyfus model of skill acquisition

Competence level	Scoring	Examples
	0	Absence of feature and /or highly inappropriate performance
	1	Minimal use of feature and /or inappropriate performance
	2	Evidence of competence, but numerous problems
	3	Competent, but some problems or inconsistencies
	4	Good features, but minor problems or inconsistencies
	5	Very good features, minimal problems or inconsistencies
	6	Excellent performance

5.3 Results

Table 21 shows the intervention fidelity scores for each item on the checklist (excluding binary item 12), broken down by HT and by coder.

The average scores for each item as scored by each coder differed by up to +0.7 to -0.9 points (out of a possible 6) with overall mean scores by coder differing by no more 0.2. Hence, there seemed to be a reasonable level of agreement between coders about the quality of intervention delivery across all processes.

The mean overall scores across the eleven scales for HT1, HT2, and HT3 were 2.9, 2.2, and 2.4 respectively suggesting no large differences in overall fidelity scores. HT1 demonstrated a better performance across all fidelity scales than

the other two HTs, with a tendency for HT2 to record lower scores on all scales other than IF1 (active participant involvement).

Table 21 Intervention fidelity scores for each process, with breakdown by trainer and by coder

	IF1	IF2	IF3	IF4	IF5	IF6	IF7	IF8	IF9	IF10	IF11	Mean <i>n</i> (SD)
Mean score (SD)	3.7 (0.8)	3.1 (1.0)	2.2 (0.9)	3.3 (0.7)	2.6 (0.8)	3.3 (0.6)	2.4 (0.7)	2.6 (1.0)	1.5 (1.1)	1.8 (1.0)	1.2 (1.0)	2.5 (0.8)
HT1 mean (SD)	4.0 (0.7)	3.8 (0.6)	2.6 (0.6)	3.6 (0.5)	2.7 (0.6)	3.5 (0.6)	2.5 (0.6)	3.1 (0.6)	1.8 (1.1)	2.2 (1.4)	1.6 (1.1)	2.9 (0.8)
HT2 mean (SD)	3.8 (0.8)	2.7 (1.0)	1.9 (0.7)	2.8 (0.7)	2.6 (0.8)	3.1 (0.6)	2.2 (0.9)	1.9 (1.2)	0.8 (0.8)	1.4 (0.8)	1.0 (0.9)	2.2 (0.9)
HT3 mean (SD)	3.4 (0.9)	2.8 (0.9)	2.0 (1.0)	3.4 (0.7)	2.6 (1.0)	3.1 (0.5)	2.4 (0.8)	2.6 (0.9)	1.7 (1.1)	1.7 (0.5)	1.0 (1.0)	2.4 (0.8)
Coder 1 mean (SD)	3.8 (0.6)	3.2 (1.1)	2.3 (0.9)	3.2 (0.8)	2.7 (0.8)	3.0 (0.5)	2.3 (0.8)	2.7 (1.0)	2.0 (1.0)	1.9 (1.0)	1.3 (0.9)	2.6 (0.7)
Coder 2 mean (SD)	4.3 (0.8)	2.9 (0.7)	2.0 (0.7)	3.9 (0.5)	2.9 (0.7)	3.6 (0.7)	2.7 (0.4)	2.6 (1.0)	1.1 (1.0)	1.6 (1.1)	1.0 (1.0)	2.6 (1.1)
Coder 3 mean (SD)	3.2 (0.8)	3.1 (0.9)	2.1 (0.8)	3.1 (0.6)	2.3 (0.7)	3.5 (0.4)	2.3 (0.8)	2.4 (1.0)	1.1 (1.0)	1.8 (1.2)	1.3 (0.9)	2.4 (0.8)

Notes: IF1: Active participant involvement; IF2: Motivation-building (smoking); IF3: Motivation-building (physical activity); IF4: Set goals (smoking); IF5: Set goals (physical activity); IF6: Review/ problem-solving (smoking); IF7: Review/ problem-solving (physical activity); IF8: Integration of concepts; IF9: Reinforce health-identity shifts; IF10: Manage social influences (smoking); IF11: Manage social influences (PA).

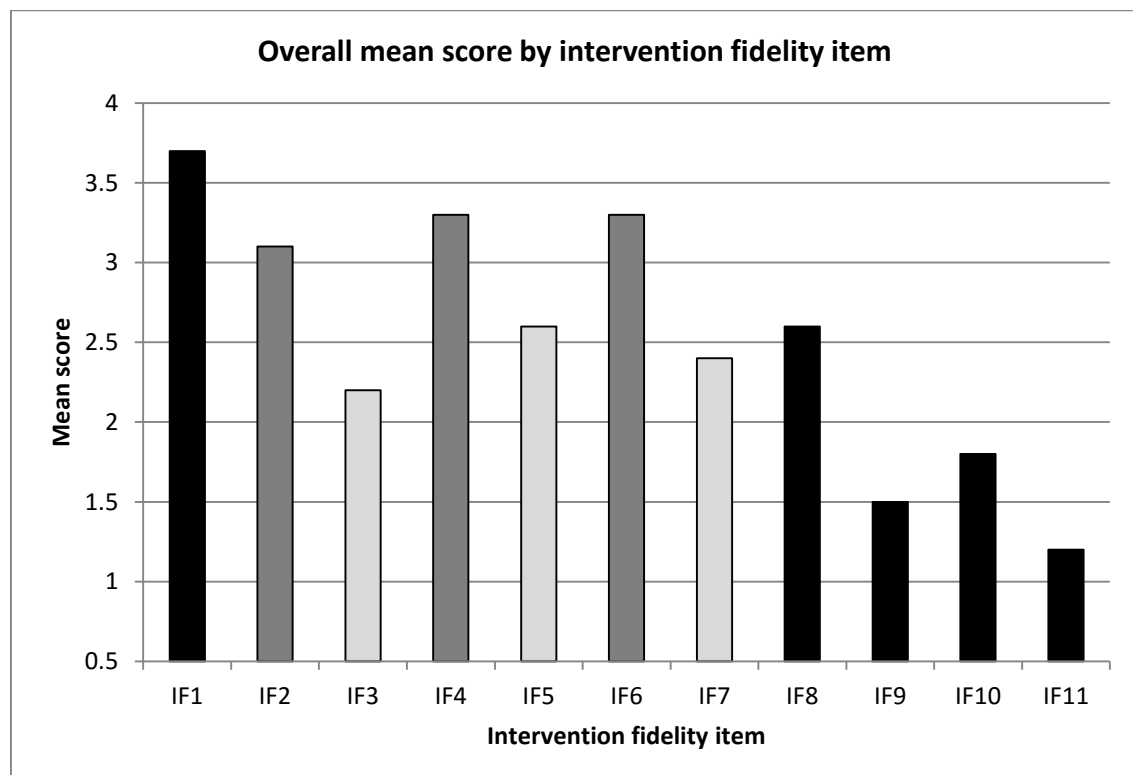
HT1: scored on 11 participants (33 sessions); HT2: scored on 8 participants (24 sessions); HT3: scored on 11 participants (33 sessions).

Coder 1: Scored 17 participants (51 sessions); Coder 2: Scored 7 participants (21 sessions); Coder 2 scored 11 participants (33 sessions). NB Some participants scored by more than one coder.

The additional twelfth scale (referral to smoking cessation services) was scored as being delivered appropriately on 29 out of the 30 participants assessed. A positive score represented the discussion and offer of referral to smoking cessation services as appropriate, not the actual acceptance of referral by the participant. There was only one reported case of potential referral being missed where the participant talked of a possible desire to make a quit attempt.

The delivery of intervention elements related to promoting physical activity (IF3, IF5, and IF7) were generally scored lower than elements relating to promoting smoking reduction (IF2, IF4, and IF6), with all smoking related items scoring above the criterion of 3 or more, and all physical activity items scoring less, highlighted graphically in *Figure 5*.

Figure 5 Mean overall fidelity scores by item



IF10 (managing social influences on smoking) and IF11 (managing social influences on physical activity) were considerably lower than expected, scoring

well below what was considered to represent acceptable practice (a score of 3 or more).

The score for IF9 (reinforce health-identity shifts) met the lower criterion of what was considered acceptable for this item of 1.5.

5.4 Discussion

Overall, intervention delivery fidelity was deemed to be acceptable for this novel pilot intervention, but with clear room for improvement in several areas. Within the pilot trial only 49 people were allocated to the intervention arm, and of these 15 (30.6%) received less than three intervention sessions, so with further experience and performance feedback improvements may have been evident. The processes relating to smoking reduction and behaviour were delivered much more successfully than those relating to increasing physical activity behaviour. This may be due to several reasons:

- 1) This primary aim of the study was focused on smoking reduction which created inherent difficulties in introducing physical activity in this context. As was shown in related qualitative work (Taylor et al., 2014) the main motivating factor for participant involvement was to address smoking behaviour and not physical activity.
- 2) There was a predominant focus on addressing smoking behaviour throughout the sessions assessed as participants were more motivated to engage in discussions around these processes than physical activity. The HTs found it difficult to convince smokers of the value of PA as a

smoking reduction technique, and therefore felt it was too difficult to deliver as part of the intervention and so avoided promoting PA.

- 3) Smokers had early success in terms of smoking reduction so later sessions focused on reinforcing this with less time and need to focus on physical activity.
- 4) The sample was already moderately active, completing more moderate physical activity per week (e.g. walking) than expected. There was little interest in increasing leisure time PA, evidenced to some extent by the low take up of subsidies to access swimming pools and gym etc. This created uncertainty for the HTs on how to best address physical activity behaviour.
- 5) None of the HTs had any prior experience of promoting either behaviour, and the satisfaction of seeing early successes in smoking reduction reinforced a tendency to focus on this rather than PA.
- 6) Adequate training was not provided to promote PA relative to smoking. For example, the four schematic approaches to smoking reduction were easier and more appealing to use than vaguer goals to increase PA.
- 7) It is possible that the sampling procedure failed to appropriately capture the later sessions where PA would have had more of a focus. The sampling had a tendency to sample two out of the three sessions analysed from the first four weeks, and only one further session from weeks five through eight. With the early focus that was seen on smoking reduction compared to PA, the lower scores relating the PA items may have been a function of the sampling methods. Limiting the sampling to only those who provided enough recorded sessions from later in the intervention would have restricted total sample.

The poorer relative delivery of the processes related to physical activity compared to smoking reduction, may in part explain the main findings which demonstrated larger changes in smoking behaviour than physical activity. The HTs found it difficult to convince the participants of the value of PA. Although IF8 (integration of concepts) scored reasonably highly in terms of delivery, the poorer delivery of physical activity related items and the quantitative data showing little support for change in physical activity, suggests that future fidelity work should also focus on fidelity of intervention receipt and enactment by participants (Bellg et al., 2004; Borrelli, 2011; Borrelli et al., 2005) as it is likely this is where the processes of change relating to physical activity and its integration with smoking reduction is failing.

Scores for IF10 and IF11 relating to managing social influences on smoking and physical activity behaviour, respectively, both scored lower than expected. This was due in part to a lack of exploration relating to social influences rather than poor delivery style. It was evident that to a certain degree that participants saw their goals and targets for behaviour change as personal and individual experiences. However, the lack of skill on the part of the HTs in exploring social influences on the two behaviours and engaging the participants successfully in this process meant that one of the key aspects of SDT underpinning the intervention went largely unaddressed (that of relatedness or companionship (Deci & Ryan, R. M., 1985; Deci & Ryan, 2000)). This lack of developing social support may have resulted in reduced intervention effects, and a greater level of smoking reduction and PA increase may be obtained by better fulfilling the requirement for participants to develop strong social support for making changes to the two behaviours in future research. Managing social influences

on physical activity (IF11) was again scored lower than its counterpart item relating to smoking behaviour, which again may go some way to explaining the reduced quantitative effects of the intervention on increasing physical activity behaviour.

All three HTs scored highly on active participant involvement. This may be due to all three having a depth of experience in working with patients in other clinical settings. The variation in overall performance of each HT across all scales could result from their different backgrounds and experience in working with disadvantaged groups. However it would not be appropriate to explore this in detail here for the risk of breaking anonymity. The limited variation in scores does support the sensitivity of the scales used to assess intervention delivery fidelity.

Although the scores for IF9 (reinforce health-identity shifts) scored within what was predetermined as a successful range for this item, there is still room for improvement. This item and related process was considered one of the more complex items and was not a key focus of the training, and as such few opportunities arose to support this shift. This was the item which reflected most explicitly the nature of the integrated multiple behaviour change approach, and certainly warrants future investigation as to how best to improve its delivery.

The examination of intervention fidelity was facilitated by the development of a clear process model (*Table 19*) and was useful in highlighting specific areas where the intervention training could be improved. However, a limitation is that we were not able to formally test the inter-rater reliability or validity of the intervention fidelity checklist. The existing data could be used to do this, but further resources and time would be required. An additional limitation was that

the fidelity measure's limited scope for judging the style and process of engagement which other data revealed the participants were very pleased with. A valid and reliable measure of intervention fidelity would be very useful for both training and quality assurance purposes if the EARS intervention is used in future projects or implemented more widely.

It is also worth reflecting on a limitation of this work that the researchers who applied the fidelity scoring to the transcripts and audio recordings were researchers who, in varying degrees, were associated with the trial in its broadest sense. This opens the possibility of researcher bias in applying the scoring checklist, particularly as the transcripts were not blinded in any way and those applying the scoring knew who the HTs were. Although every assurance was made that the scoring was completed impartially, it cannot be ignored that some inherent bias may exist. Future research should employ researchers who are completely independent from the trial to apply the fidelity scoring to the transcripts and audio recordings.

Whilst the rigorous approach taken here to assessing intervention delivery fidelity had its strengths, it contains a fundamental problem in its application which became evident through the application of the scales. The effectiveness of complex interventions may be dependent on the skills of those delivering them (Cross & West, 2011). 'Skills' has been characterised by the separate but related constructs of 'adherence' and 'competence' (Mars et al., 2013), where adherence represents the extent to which practitioners deliver what they were trained to do and was outlined by the intervention designers, and competence refers to the ability of the practitioner to deliver the predetermined intervention with a particular focus on their ability to respond to a variety of resistance and

situational cues. These two behaviours of adherence to treatment components and competence to deliver the treatment in the manner specified have been shown to have low correlations (Miller & Binder, 2002; Perepletchikova & Kazdin, 2006) and should be assessed separately (Borrelli, 2011). The methods for assessing the 11 items within this research did not allow for a distinction between these two constructs, and as such there was discussion amongst the research team as to the best way to score items when, for example, when adherence was high but competence in delivery was low. The attempt to integrate both aspects into the Dreyfus scoring system worked reasonably well, although this research could be strengthened by the addition or separation of adherence and competence scores for each of the processes, as has been successfully implemented elsewhere (Barber, Mercer, Krakauer, & Calvo, 1996; Mars et al., 2013). The addition of assessment of non-specific factors (e.g. empathy, communication and therapeutic style), not just active patient involvement, should also be considered for future research (Borrelli, 2011).

The inclusion of a variety of formal behaviour techniques into both the HT training and the intervention manual and delivery formed a key part (theoretically) of successful delivery of the eleven processes assessed as part of the delivery fidelity (see *Table 19* and *20*). Whilst use of the identified behaviour change techniques did inform the fidelity assessment to a degree (see *Appendix 5*), there was no formal assessment or behaviour change technique mapping against the eleven processes in order to explicitly assess the extent to which the techniques were delivered. This would be particularly important if assessed across time as a participant moves through the intervention. This element of adherence to a delivery protocol would be an important part of future fidelity assessment, and would contribute towards

unpicking the complexities of assessing 'adherence' and 'competence' as separate measures.

One of the key benefits of rigorous treatment fidelity assessment is to allow for the early detection of errors to prevent protocol deviations from becoming widespread and long lasting which has the potential to influence a study's findings (Borrelli, 2011). Monitoring implementation fidelity early on in a study can improve the fidelity of implementation longer term (Dufrene, Noell, Gilbertson, & Duhon, 2005) which can result in improved treatment retention and reduced attrition (Noel, 2006). Within this pilot study the fluid nature of the novel intervention to be able to adapt to uncertainties was key to its design. Due to the reactive nature of the intervention, early and ongoing assessment of implementation fidelity would have been problematic as the identification of the key processes was ongoing and as such assessing their delivery would not have been possible with any degree of rigour. The processes and their assessment outlined here as a result of this pilot work should be incorporated as part of any future research from the very beginning. This has the potential to increase implementation fidelity in terms of both adherence and competence and strengthen several aspects of the study overall.

5.5 Recommendations for future research

Future research of this nature should consider the following in regards to practitioner training:

- 1) Additional training to address physical activity behaviour (particularly amongst those who may already be physically active) as part of the process would be appropriate in similar future work.

- 2) A stronger emphasis on training and feedback on exploring and managing social influences on behaviour.
- 3) Assessment of previous experience of the HTs in working with such a population would be an important part of future training in order to create a more individualized training programme.
- 4) Additional training and development to aid the HTs in reinforcing positive identity shifts.

Methodological considerations for assessing intervention fidelity of future research of this kind should consider:

- 1) The addition of assessing fidelity relating to intervention receipt and enactment by participants to strengthen understanding relating to the integration of concepts beyond delivery.
- 2) The development of a way to assess adherence and competence separately as reported in other literature.
- 3) Taking steps to ensure robust methods of inter-rater reliability can be taken.
- 4) Employing independent researchers to complete the fidelity assessment.
- 5) A sampling procedure which will allow for greater number of session from the later stages of the intervention to be assessed.

5.6 Conclusion

Intervention fidelity was examined and deemed to be acceptable overall in the context of a pilot study, with substantial recommendations for future training and methods for assessing intervention fidelity. Future research and interventions of

this kind may benefit from a more rigorously stepped approach to introducing behaviours, introducing PA more explicitly later in the intervention following successful changes in smoking behaviour.

6. GENERAL DISCUSSION

6.1 Outline

In summary, this thesis presents additional in depth examinations of the pragmatic and theoretical challenges faced within a phase 2 pilot pragmatic randomised controlled trial examining the feasibility of a client centred multiple behaviour change intervention among disadvantaged smokers not wishing to quit immediately. It represents the culmination of individually led research within the broader setting of a pilot randomised controlled trial and provides detailed information and pragmatic recommendations for future research of this kind, focusing on issues surrounding recruitment, study attrition, data analyses, and the assessment of intervention fidelity.

This final chapter provides an overview of all the research undertaken as part of this thesis, bringing together the wider implications for policy, practice and future research.

6.2 Overview of aims and unique contribution

The overall aim of this thesis was to extend the research beyond that of the commissioned trial and that which was presented within the broader trial's main report. Chapter 2 aimed to examine in detail the issues related to recruiting disadvantaged groups and provides unique data on potential recruitment rates of disadvantaged groups into a research trial via different methods and a descriptive comparison of the population recruited. Chapter 3 sought to identify factors associated with participant attrition in the pilot trial to inform the methods to reduce attrition in a definitive trial. It revealed some participant characteristics

which were associated with attrition and explored the relationship between characteristics and time of drop-out, identifying potential issues for retention of participants in future research. Chapter 4 quantitatively examined the effects of the intervention on selected smoking and physical activity variables, and took steps towards identifying the effects of various intention to treat analyses on outcomes, an issue which is prevalent in smoking related research. Chapter 5 took an in depth approach to examining intervention fidelity (an area itself which is under reported) and evaluated the methods used within the pilot trial. It identifies key areas where fidelity could be considered to be low and makes recommendations for the future assessment of fidelity within such a trial.

6.3 Main findings

6.3.1 Recruitment

The main findings related to the recruitment of disadvantaged groups into a research trial of this kind were:

- Invitation letters sent from primary care with no follow-up telephone calls resulted in 5.1% of those invited into the trial being randomised. With the addition of follow-up telephone calls this was increased to 8.8%.
- To recruit one participant via primary care by invitation letter only requires 18 minutes of researcher time, this number increases to 145 minutes with follow up telephone calls.
- Invitation letters sent from Stop Smoking Services with no follow-up telephone calls resulted in 6.8% of those invited into the trial being

randomised. With the addition of follow-up telephone calls this was increased to 11.1%.

- To recruit one participant via the Stop Smoking Services by invitation letter only requires 24 minutes of researcher time, this number increases to 157 minutes with follow up telephone calls.
- Those recruited through Stop Smoking Services, compared to primary care, were more likely to be recruited through letter invitation, to have used smoking cessation aids before, and to have made a quit attempt in the past year.
- Those recruited via initial invitation letter, compared to those recruited through follow-up telephone calls, were more likely to have used Stop Smoking Services in the past year and to self-report completing at least 30 minutes of moderate and vigorous physical activity in the past week.
- Reasons for ineligibility were similar across recruitment sites and methods.
- Qualitatively, the appeal of the invitation to participants was the key message of smoking reduction as opposed to smoking cessation, and appealed to some people who were skeptical of, or had had previous bad experiences with, the Stop Smoking Services. There was support that the message to reduce reached those who would not have been interested in quitting.
- Community based approaches to recruitment were largely unsuccessful and resource intensive.
- Overall, it is possible to recruit a disadvantaged population (as per a predefined definition) via the methods employed within the study.

6.3.2 Attrition

The main findings related to examining factors influencing study attrition were:

- 61.6% (n=61) were followed up at 16 weeks post baseline.
- The majority of attrition occurred immediately after baseline with 21 out of 38 of those who dropped out dropping out before week 4.
- Univariable analysis showed those with high self-reported confidence to quit in the next six months were less likely to withdraw than those with low confidence, and those who were completing at least 150 minutes of self-reported moderate and vigorous physical activity per week compared to those completing less than 150 minutes per week were less likely to withdraw.
- Exploratory analysis revealed that those who were lost to follow-up early in the trial (i.e., by 4 weeks), compared with those completing the study, were younger, had smoked for fewer years and had lower confidence to quit in the next 6 months.
- Participants who recorded a higher expired air carbon monoxide reading at baseline were more likely to drop out late in the study, as were those recruited via follow-up telephone calls.
- Multivariable analyses showed that only completing less than 150 minutes of physical activity retained any confidence in predicting attrition in the presence of other variables.
- Exploratory analyses of change in number of cigarettes smoked from baseline to either week 4 or week 8 showed no significance in predicting dropout before week 16.

6.3.3 Smoking and physical activity intervention outcomes

The main findings from the examination of the main intervention effects on smoking and physical activity related outcomes were:

- Compared with controls, intervention smokers made more quit attempts (36 v 10%), and a greater proportion achieved $\geq 50\%$ reduction in cigarettes smoked (63 v 32%).
- Post-quit abstinence measured by exhaled carbon monoxide at 4 week follow-up showed promising differences between groups (23% v 6%).
- Limited evidence was found for the intervention on increasing self-reported physical activity levels, with only secondary analyses revealing any positive differences between the two arms.
- Secondary analyses suggested that the standard missing data assumption of 'missing' being equivalent to 'smoking' may be conservative resulting in a reduced intervention effects.

6.3.4 Intervention fidelity assessment

The main findings from the assessment and evaluation of intervention fidelity assessment were:

- Overall intervention fidelity was considered to be acceptable.
- There was evidence for sensitivity in the scales used to assess fidelity.
- Good agreement between coders was observed.
- Processes related to smoking behaviour were generally better delivered than those related to physical activity.

- Items related to engaging and managing social influence scored lower than expected.
- Methodological improvements for future fidelity assessment were identified.
-

6.4 Discussion

Each chapter presented an in depth discussion relating specifically to the content of that chapter. This section aims to integrate the findings in a broader sense.

For some time reducing health inequalities in England has been a key theme underpinning health provision and is becoming increasingly central to policy objectives across the National Health Service (NHS), local government, the third and private sectors, and community groups (Department of Health, 2002; Gray, 1982; Marmot et al., 2010). Health inequalities are associated with direct and indirect economic costs of around £70bn yearly in England and result in an average difference in life expectancy and disability free life expectancy of 7 and 17 years, respectively, between those living in the most and least deprived areas (Marmot et al., 2010). The clustering of multiple unhealthy behaviours (smoking, physical inactivity, poor diet, and alcohol consumption) in England have reduced overall between 2003 and 2008, yet these reductions have been seen mainly among those of high socioeconomic status (SES) resulting in a widening of health inequalities (Buck & Frosini, 2012) suggesting more needs to be done to tackle health inequality.

A recent review (Hiscock, Bauld, Amos, & Platt, 2012) revealed that evidence for interventions that work among lower socioeconomic groups is sparse and that interventions should be delivered in conjunction with broader attempts to tackle health inequality. This coupled with an earlier review (Michie, Jochelson, et al., 2009) which highlighted a lack of information for the designing of interventions for disadvantaged groups (but interventions *can* be effective in such groups) demonstrates a lack of detailed information for firstly accessing disadvantaged groups and secondly designing effective targeted interventions.

Multiple health behaviour risks in individuals put them at greatest risk for chronic disease, disability, and premature death (Doll, Peto, Boreham, & Sutherland, 2004; Kvaavik, Batty, Ursin, Huxley, & Gale, 2010; Mokdad, Marks, Stroup, & Gerberding, 2004), and the number of risky health behaviours (smoking, alcohol consumption, physical inactivity, and poor diet) is associated with mortality risk (Khaw et al., 2008). In the UK, around 25% of adults engage in at least three of these risky behaviours (Poortinga, 2007), and those with multiple risky health behaviours are the highest cost population with increased health care, disability costs, and decreased productivity (Edington, 2001). In light of the burden of multiple risky behaviours, multiple health behaviour change (MHBC) research has gained increased attention in recent years and may present the 'future' of preventive medicine (James O Prochaska, 2008), presenting one of the greatest challenges in health behaviour change (Yin et al., 2013). A growing body of evidence in MHBC interventions (those that target more than one behaviour either simultaneously or sequentially (J. J. Prochaska, Spring, & Nigg, 2008)) in supporting positive change in multiple behaviours amongst a variety of populations (A. C. Green, Hayman, & Cooley, 2015; Johnson et al., 2008, 2014; Jones et al., 2003; James O. Prochaska et al., 2004, 2005) suggests

addressing multiple behaviours is feasible, and has been shown to be as effective as individual behaviour change interventions on certain behaviours (J. Prochaska, Velicer, Prochaska, Delucchi, & Hall, 2006). There is a well reported socio-demographic gradient in the prevalence of multiple risk factors (Berrigan, Dodd, Troiano, Krebs-Smith, & Barbash, 2003; Chiolerio, Wietlisbach, Ruffieux, Paccaud, & Cornuz, 2006; Laaksonen, Prättälä, & Lahelma, 2003; Poortinga, 2007; Schuit, van Loon, Tijhuis, & Ocké, 2002; Shankar, McMunn, & Steptoe, 2010), and also evidence that long term multiple health behaviour change is related to treatment, stage of change, problem severity and effort effects but not to any demographic variable (Blissmer et al., 2010), suggesting MHBC interventions among low socioeconomic groups could be effective and aid in tackling health inequalities. However, understanding of MHBC and its implications for practice remains relatively undeveloped (Mc Sharry, Olander, & French, 2014; Nigg & Long, 2012; J. J. Prochaska et al., 2008) with queries over whether behaviours should be addressed simultaneously or sequentially, separately or integrated, and over what time period (McEwen et al., 2006; James O Prochaska, 2008). It has recently been reported that single health behaviour change interventions may draw on different behaviour change techniques than MHBC interventions (Mc Sharry et al., 2014) which has fundamental implications for how interventions are designed and how they are delivered. The presentation of fidelity assessment within this thesis provides a novel insight and method into assessing multiple behaviours as delivered within a pragmatic exploratory trial.

As discussed throughout this thesis, smokers from disadvantaged groups (e.g., unemployed, low-skilled manual workers, people with mental health problems) attempt to quit at the same rate as others but their success in quitting is lower

(Hiscock, Bauld, Amos, Fidler, et al., 2012). Smoking has been identified as one of the main contributing factors to health inequalities in industrial countries (Chandola et al., 2004) and in England and Wales accounts for nearly half the difference of smoking-attributed mortality (among males) between the highest and lowest socioeconomic groups (Jha et al., 2006).

Given the enormity of the problem of health inequality, addressing the priority areas such as smoking among disadvantaged groups, warrants continued and rigorous research. To date, the evidence base for effectively accessing, engaging, and affecting the behaviour of those groups remains surprisingly underdeveloped (Bryant et al., 2011; Hiscock, Bauld, Amos, Fidler, et al., 2012; Michie, Jochelson, et al., 2009; Ranney et al., 2006). This thesis provides a systematic evaluation of methods involved in a multiple behaviour change trial aimed at disadvantaged groups, by assessing recruitment methods (accessing disadvantaged groups), attrition (engagement), outcomes (affecting behaviour), and intervention delivery in addressing multiple behaviours (to aid in designing future trials).

Within the context of the EARS pilot trial, a disadvantaged population was successfully recruited (except for the target relating to single parents) according to a predetermined definition of what constituted a disadvantaged population (the target was 75% were unemployed or in social class C2–E (skilled manual workers, semi-skilled and unskilled manual workers, state pensioners, casual and lowest grade workers, and those unemployed with state benefits only), 30% were single parents, and 20% had indicators of a mental health problem, indicated within the trial by answering ‘moderately’ or ‘extremely’ anxious or depressed to item 5 of the EQ-5D questionnaire). Successful recruitment

methods were identified and are in line with what other limited research has been published on recruitment rates of disadvantaged groups (Carlini et al., 2012; Choudhury et al., 2012; Lowther et al., 2002; Toobert et al., 2010). Detailed methods of the recruitment approaches and their impact on the characteristics on who was recruited allows for more reliable future planning of such research. Of those who were recruited, this research has identified those who were then more likely to drop out, identifying the potentially harder to reach groups within the predefined disadvantaged population. This provides valuable information relating the design and implementation of future research, highlighting the potential challenges of engaging with participants with certain characteristics. Study attrition was found to be acceptable when compared to other research in similar areas (see Chapter 3). Progressing from this, an examination of the feasibility of handling missing data as a result of attrition revealed that the application of more advanced intention to treat analyses in relation to smoking status (such as multiple imputation) is possible, and perhaps more desirable. Finally, a rigorous approach to assessing intervention fidelity was applied, and in this relatively under-evaluated area recommendations for improvement are presented in line with more developed fidelity work.

Whilst this thesis attempts to apply a systematic approach to assessing various aspects of the EARS pilot trial and make pragmatic recommendations, there are fundamental ways it could be improved. It is clear that within the context of the EARS pilot trial, its aims and objectives were achieved. However, there are specific areas in which the approach could be improved. As discussed in chapter 5, the only fidelity assessment which took place focussed on intervention delivery. It should be recognised that future research of this kind should employ a more comprehensive assessment of fidelity by evaluating all

domains (Study Design, Provider Training, Treatment Delivery, Treatment Receipt, and Treatment Enactment) to improve overall confidence in the trial's efficacy (Bellg et al., 2004; Borrelli et al., 2005). Additionally, a more systematic framework should be applied for assessing and evaluating the research, such as the RE-AIM framework (Glasgow et al., 1999) which is designed to enhance the quality, speed, and public health impact of efforts to translate research into practice, such as the EARS study. RE-AIM outlines five steps of: (1) Reach, (2) Efficacy, (3) Adoption, (4) Implementation, and (5) Maintenance, and whilst within the context of EARS as a pilot trial they may not all be applicable, future developments of projects such as EARS should adopt this more robust approach. Such a framework is appropriate for applied research, and would strengthen future research due to its focus on evaluating reach and impact, emphasising the translational impact from experimental evidence through to policy (as opposed to models such as the precede-proceed model (Green & Kreuter, 2005) which is more focused on the planning and internal evaluation of research). The domain of 'reach' is perhaps the most applicable to the current study, but within the trial this was undervalued due to restraints from the initial ethical approval. It was not possible to determine the proportion of the targeted population that participated in the intervention as ethical approval was not gained for profiling those who did not respond to the invitation to participate in the trial. Considering research this area is particularly lacking among disadvantaged groups (Gaglio et al., 2013), it should be important consideration and an integral part of future research when attempting to access such populations.

6.5 Limitations

6.5.1 Threats to external validity

A prevailing limitation of the study was its lack of ethnic diversity in the sample (97% White British). This is more than likely due to the research setting (Plymouth, UK) where ethnic diversity is low; however it does limit the research's generalisability to other settings which are more ethnically diverse.

The study did not attempt to recruit homeless or other disadvantaged smokers who were not registered with a GP, and excluded those with serious mental illness or on-going substance misuse. These are all groups who demonstrate higher levels of smoking and could potentially gain from an intervention to support reduction.

6.5.2 Threats to internal validity

In examining study attrition, those who were lost to follow up were not followed up by interview. By putting in place procedures and increasing capacity in order to attempt to interview those lost to follow up may have helped better understand qualitatively individual reason for withdrawal. It must be recognised though that this is likely to be problematic as those participants who become un-contactable without giving a reason for withdrawal are unlikely to be able to be contacted for other reason relating to the research.

The low number of observations relating to study attrition results in a lack of precision regarding the results. It does however provide an insight into the considerations that may need to be taken into account when planning a larger trial.

The numbers involved in the analyses of the smoking and physical activity outcomes are likely insufficient to draw any conclusive effects of the intervention on the identified outcomes. The work does, however, provide an insight and methodological framework for applying such methods in future work of this kind.

The intervention fidelity assessment does not consist of any formal inter-rater reliability analyses and therefore does not evaluate any potential bias between raters. The overall results showed little variation between raters which suggests limited bias, but future research should incorporate this into its design.

6.6 Future research

Based on the recommendations outlined in this thesis, future research should consider the following:

- Invitations to potential participants should be sent from local GP practices in order to have some level of confidence in recruitment rates. The time and resource associated with this approach should be factored in in order to allow for effective costing. A similar approach is possible from Stop Smoking Services, although it may not access as much of a 'hard to reach' or disadvantaged population.
- Care should be taken when using GP practice data bases as there is the potential for these records to be inaccurate and out of date. This should be accounted for when planning recruitment.
- The message of reduction as opposed to cessation is an effective tool for recruiting those who may not engage with traditional cessation services, and provides an opportunity to increase the reach of services in future research, particularly among the disadvantaged.

- Future community based approaches should invest more time in integrating the recruitment within the community. Care should be taken as these approaches are considerably more resource intensive. More research is needed on the best approaches.
- Those who enter the trial and demonstrate low-confidence to quit and are less physically active at baseline are potentially more likely to drop out. More effort should be made to ensure retention of such participants, possibly through the adaptation of the delivered intervention based on baseline values.
- Procedures should be put in place (and resource allowed for) to enable to systematic following up of those who drop out of the study without giving a reason, in order to qualitatively strengthen the understanding of why people withdraw.
- A variety of approaches to handling missing data should be employed to continue to investigate the effects of missing data on outcomes. Where possible, those who are lost to follow up should be contacted to obtain smoking status in order to further the understanding of whether 'assumed smoking' is a realistic approach to handling missing data.
- Fidelity assessment methods should incorporate a more inclusive approach, by systematically assessing both adherence to intervention delivery as well as practitioner competence. This should be used throughout the trial in order to provide ongoing feedback and training for practitioners and to identify early on any deviations from the protocol.
- Inter rater reliability checks (kappa statistics) should be factored in and resource should be allocated for this.

- Future training of practitioners within a trial of this type should reconsider the processes relating to physical activity and how they can best be incorporated more effectively. Potentially through employing a more rigorously stepped approach to multiple behaviour change.
- Further exploration of the best ways to promote the management of and engaging with social support is needed. Both through practitioner training and possible ways of removing barriers for participants to engage with others.
- Fidelity assessment of all five domains should be considered in order to rigorously assess fidelity.
- Progression to a full definitive trial should more rigorously employ a framework such as the RE-AIM framework to maximise efficiency and seamless transition into practice.

6.7 Conclusions

The findings from this programme of study support the successful delivery of a phase II pilot randomised controlled trial to explore the role of physical activity in supporting smoking reduction. It has explored the methodological and pragmatic implications resulting from detailed research beyond the scope of the original study, specifically:

- 1) Using General Practice lists is a powerful way of recruiting disadvantaged patients to health interventions in an area of deprivation, and much more effective than community approaches. It provides important and pragmatic information for the future recruitment of disadvantage populations into research trials.

- 2) The present research provides important information on factors that may influence attrition within a multi-component smoking reduction study among low socioeconomic status smokers. Retention was at least comparable with the few other studies involving disadvantaged groups with smoking behaviour as a main outcome. These analyses provide unique information on retention in a study aimed at smokers in these groups who did not wish to quit. Only a few factors were quantitatively associated with attrition, suggesting that further research is needed to explain why participants in this type of study drop out.
- 3) This study presents encouraging findings from a pilot pragmatic randomised controlled trial and adds to the limited literature on the role of physical activity for smoking reduction, rather than abrupt quitting. A fully powered trial to test the effectiveness of a counselling-based intervention with a focus on physical activity and smoking reduction among disadvantaged groups is now needed. Such a trial should examine the mediating role of changes in physical activity on smoking reduction as well as qualitatively explore how physical activity can help in self-regulation of smoking.
- 4) Intervention fidelity was examined and deemed to be acceptable overall in the context of a pilot study, with substantial recommendations for future training and methods for assessing intervention fidelity. Future research and interventions of this kind may benefit from a more rigorously stepped approach to introducing behaviours, introducing PA more explicitly later in the intervention following successful changes in smoking behaviour.

Through a mixed methods approach it supports the main trial's conclusions that there is indicative support for the intervention in affecting smoking and physical activity outcomes, and that the study methods were feasible and acceptable.

This thesis provides detailed recommendations for the progression of the research from a pilot trial to a definitive trial, which based on the findings, is warranted and feasible.

6.8 Implications for policy and practice

- Due to the nature of the research being conducted within a pilot trial, it is premature to draw any conclusions for informing policy. The thesis does however present several important examples to inform future research, in particular: A robust and transparent approach to documenting recruitment activity in line with emerging criteria for assessing trials in terms of recruitment quality (Foster et al., 2011).
- A detailed examination and approach to investigating predictors of attrition.
- It contributes further to the impact of assumptions and subsequent analyses carried out in the presence of missing data (Hedeker et al., 2007; White, Royston, & Wood, 2011; Wood et al., 2005).
- It provides an example of fidelity assessment of a multiple health behavior change intervention, contributing to an emerging field of research which continues to gain momentum (Bellg et al., 2004; Borrelli et al., 2005).

APPENDICES

Appendix 1 Ethical Approval

South West 3 REC
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08 November 2010

Professor Adrian Taylor
Professor in Exercise & Health Psychology
University of Exeter
Sport and Health Sciences
Heavitree Road,
Exeter EX1 2LU

Dear Professor Taylor

Study Title: An exploratory trial to evaluate the effects of a physical activity intervention as a smoking cessation induction and cessation aid among the 'hard to reach'. Trial acronym: EARS (Exercise Assisted Reduction then Stop smoking)
REC reference number: 10/H0106/59

Thank you for your email of 15 October 2010, submitting revised documentation in response to the Committee's request for further information on the above research.

The further information was considered in correspondence by a sub-committee of the REC. A list of the sub-committee members is attached.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. I will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where the only involvement of the NHS organisation is as a Participant Identification Centre (PIC), management permission for research is not required but the R&D office should be notified of the study and agree to the organisation's involvement. Guidance on procedures for PICs is available in IRAS. Further advice should be sought from the R&D office where necessary.

Sponsors are not required to notify the Committee of approvals from host organisations.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Investigator CV		
Protocol	1	04 August 2010
Letter of Invitation from GP	1	04 August 2010
REC application	3.0	04 August 2010
Covering Letter		04 August 2010
Summary/Synopsis	Recruitment flow chart	04 August 2010
Questionnaire: Demographics	1	04 August 2010
Questionnaire: mCEQ	1	04 August 2010
Advertisement	1	04 August 2010
Letter of invitation to participant	1. Phase 1	04 August 2010
Participant Information Sheet	. Phase 1	04 August 2010
Participant Information Sheet	2a	
Response to Request for Further Information	Email	15 October 2010
Participant Information Sheet	1. Phase 2	04 August 2010
Participant Consent Form	1. Phase 1	04 August 2010
Participant Consent Form	1. Phase 2	04 August 2010
Questionnaire: Smoking history, quitting & cessation aids used	1	04 August 2010
Questionnaire: PSS	1	04 August 2010
Questionnaire: Smoking dependence and status	1	04 August 2010
Questionnaire: PAR-Q	1	04 August 2010

Questionnaire: Alcohol consumption	1	04 August 2010
Questionnaire: Self reported physical activity	1	04 August 2010
Questionnaire: Self reported cravings and withdrawal symptoms	1	04 August 2010
Questionnaire: EQ-5D	1	04 August 2010
Letter from funder		30 June 2010
Questionnaire - SF-12	1	04 August 2010
Evidence of insurance or indemnity	Letter from Marsh	02 August 2010
Evidence of insurance or indemnity	Ins. cert.	27 July 2010
Letter from Statistician		15 July 2010

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "*After ethical review – guidance for researchers*" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

10/H0106/59	Please quote this number on all correspondence
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Yours sincerely

Dr Pamela Cairns
Chair

Enclosures: "After ethical review – guidance for researchers"

Copy to: Dr Lee Bridger
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South West 3 REC

Attendance at Sub-Committee of the REC meeting on 01 November 2010

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mrs Nicola Henderson	Trust Patient Safety Manager	Yes	
Dr Margrid Schindler	Consultant Senior Lecturer	Yes	

Appendix 2 STATA commands and output for study attrition analyses (logistic and multinomial logistic regression, including models)

```
. do "C:\Users\Tommy\OneDrive\Work\EARS\Output\papers\Attrition Papers\STATA Files\LOG REG MODEL.do"
```

```
. logistic withdrawal i.arm2 age_years i.b_gender baselinecompositecigs stop_
> period i.qa24_pastyear smoke_years i.b_smoke_cohabitants ftnd_baseline i.b_m
> odvig_day_30 b_conf_quitHIGHLOW
```

```
Logistic regression                                Number of obs   =          97
                                                    LR chi2(12)    =         15.16
                                                    Prob > chi2    =         0.2327
Log likelihood = -57.363399                        Pseudo R2      =         0.1167
```

withdrawal	Odds Ratio	Std. Err.	z	P> z	[95% Conf. Interval]	
arm2						
I	1.004952	.4845627	0.01	0.992	.3905865	2.585672
age_years	.9463712	.0689307	-0.76	0.449	.8204699	1.091592
b_gender						
Female	1.121945	.54692	0.24	0.813	.4315514	2.916829
baselinecom~s	.985771	.0176538	-0.80	0.424	.9517704	1.020986
stop_period	1.002374	.006252	0.38	0.704	.9901947	1.014703
1.qa24_pastyear	.9583345	.5275392	-0.08	0.938	.3258007	2.818917
smoke_years	1.027678	.0689828	0.41	0.684	.9009905	1.172179
b_smoke_coh~s						
No	2.940614	1.822412	1.74	0.082	.8728013	9.907421
NA	1.24225	.7416516	0.36	0.716	.385498	4.003094
ftnd_baseline	1.140156	.135473	1.10	0.270	.9032851	1.439143
1.b_modvig~30	.4331012	.2143905	-1.69	0.091	.1641474	1.142733
b_conf_quit~W	.3846343	.1920091	-1.91	0.056	.1445869	1.023216
_cons	9.49119	19.7264	1.08	0.279	.1615071	557.7631

```
.
end of do-file
```

```
. do "C:\Users\Tommy\OneDrive\Work\EARS\Output\papers\Attrition Papers\STATA Files\Multinomial logistic regression all variables.do"
```

```
. *Multinomial logistic regression model for early withdrawal, late withdrawal,
> no withdrawal - all participants
```

```
. mlogit withdrawal_time i.arm2, base
```

```
Iteration 0:  log likelihood = -92.053961
Iteration 1:  log likelihood = -91.571935
Iteration 2:  log likelihood = -91.569697
Iteration 3:  log likelihood = -91.569697
```

```
Multinomial logistic regression                                Number of obs   =          99
                                                    LR chi2(2)     =          0.97
                                                    Prob > chi2    =         0.6162
Log likelihood = -91.569697                        Pseudo R2      =         0.0053
```

withdrawal~e	Coef.	Std. Err.	z	P> z	[95% Conf. Interval]	
--------------	-------	-----------	---	------	----------------------	--

0		(base outcome)					
1							
	arm2						
	C		0	(base)			
	I		-.2548922	.5099371	-0.50	0.617	-1.254351 .7445661
	_cons		-.9490806	.3399873	-2.79	0.005	-1.615444 -.2827176
2							
	arm2						
	C		0	(base)			
	I		.3894648	.5553814	0.70	0.483	-.6990628 1.477992
	_cons		-1.488077	.4184677	-3.56	0.000	-2.308259 -.6678955

```
. mlogit withdrawal_time i.rec_avenue2, base
```

```
Iteration 0: log likelihood = -92.053961
Iteration 1: log likelihood = -91.901591
Iteration 2: log likelihood = -91.901309
Iteration 3: log likelihood = -91.901309
```

Multinomial logistic regression	Number of obs	=	99
	LR chi2(4)	=	0.31
	Prob > chi2	=	0.9895
Log likelihood = -91.901309	Pseudo R2	=	0.0017

withdrawal~e	Coef.	Std. Err.	z	P> z	[95% Conf. Interval]
0		(base outcome)			
1					
	rec_avenue2				
	Primary care		0	(base)	
	SSS		-.2321122	.5613575	-0.41 0.679 -1.332353 .8681283
	Comunity		-.4144338	1.16123	-0.36 0.721 -2.690403 1.861536
	_cons		-.9718606	.3137764	-3.10 0.002 -1.586851 -.3568702
2					
	rec_avenue2				
	Primary care		0	(base)	
	SSS		-.1732717	.6065774	-0.29 0.775 -1.362142 1.015598
	Comunity		-.1732717	1.169588	-0.15 0.882 -2.465622 2.119079
	_cons		-1.213023	.3434183	-3.53 0.000 -1.88611 -.5399352

```
. mlogit withdrawal_time i.rec_method, base
```

```
Iteration 0: log likelihood = -92.053961
Iteration 1: log likelihood = -89.78608
Iteration 2: log likelihood = -89.736117
Iteration 3: log likelihood = -89.736087
Iteration 4: log likelihood = -89.736087
```

Multinomial logistic regression	Number of obs	=	99
	LR chi2(4)	=	4.64
	Prob > chi2	=	0.3268
Log likelihood = -89.736087	Pseudo R2	=	0.0252

withdrawal~e	Coef.	Std. Err.	z	P> z	[95% Conf. Interval]
0		(base outcome)			
1					

rec_method							
Letter		0	(base)				
Phone		.4924765	.5300637	0.93	0.353	-.5464294	1.531382
NA		-.1466035	1.169284	-0.13	0.900	-2.438358	2.145151
_cons		-1.239691	.3423812	-3.62	0.000	-1.910746	-.5686361

2							
rec_method							
Letter		0	(base)				
Phone		1.203973	.5878895	2.05	0.041	.0517306	2.356215
NA		.4595323	1.201242	0.38	0.702	-1.894859	2.813923
_cons		-1.845827	.4392977	-4.20	0.000	-2.706834	-.984819

```
. mlogit withdrawal_time age_years, base
```

```
Iteration 0:  log likelihood = -92.053961
Iteration 1:  log likelihood = -88.770219
Iteration 2:  log likelihood = -88.669273
Iteration 3:  log likelihood = -88.669168
Iteration 4:  log likelihood = -88.669168
```

Multinomial logistic regression	Number of obs	=	99
	LR chi2(2)	=	6.77
	Prob > chi2	=	0.0339
Log likelihood = -88.669168	Pseudo R2	=	0.0368

withdrawal~e		Coef.	Std. Err.	z	P> z	[95% Conf. Interval]	

0		(base outcome)					

1							
age_years		-.0573953	.0235938	-2.43	0.015	-.1036383	-.0111523
_cons		1.492189	1.048991	1.42	0.155	-.5637964	3.548174

2							
age_years		.001098	.0255684	0.04	0.966	-.0490151	.0512111
_cons		-1.330553	1.262735	-1.05	0.292	-3.805468	1.144361

```
. mlogit withdrawal_time i.b_gender, base
```

```
Iteration 0:  log likelihood = -92.053961
Iteration 1:  log likelihood = -91.489714
Iteration 2:  log likelihood = -91.488893
Iteration 3:  log likelihood = -91.488893
```

Multinomial logistic regression	Number of obs	=	99
	LR chi2(2)	=	1.13
	Prob > chi2	=	0.5683
Log likelihood = -91.488893	Pseudo R2	=	0.0061

withdrawal~e	Coef.	Std. Err.	z	P> z	[95% Conf. Interval]	

0	(base outcome)					

1						
b_gender						
Male	0	(base)				
Female	.3870677	.5173547	0.75	0.454	-.6269287	1.401064
_cons	-1.287854	.3993529	-3.22	0.001	-2.070572	-.5051369

2						
b_gender						
Male	0	(base)				

Female		.5076957	.5686022	0.89	0.372	-.6067442	1.622136
_cons		-1.575536	.4484969	-3.51	0.000	-2.454574	-.6964987

```
. mlogit withdrawal_time bmi_baseline, base
```

```
Iteration 0:  log likelihood = -91.566541
Iteration 1:  log likelihood = -91.299574
Iteration 2:  log likelihood = -91.298481
Iteration 3:  log likelihood = -91.298481
```

Multinomial logistic regression	Number of obs	=	98
	LR chi2(2)	=	0.54
	Prob > chi2	=	0.7649
Log likelihood = -91.298481	Pseudo R2	=	0.0029

withdrawal~e	Coef.	Std. Err.	z	P> z	[95% Conf. Interval]	
0	(base outcome)					
1						
bmi_baseline	.0227796	.0385137	0.59	0.554	-.0527058 .0982651	
_cons	-1.698771	1.134239	-1.50	0.134	-3.921839 .5242967	
2						
bmi_baseline	-.0127661	.0453235	-0.28	0.778	-.1015985 .0760664	
_cons	-.9065599	1.282419	-0.71	0.480	-3.420056 1.606936	

```
. mlogit withdrawal_time i.b_employment_status, base
```

```
Iteration 0:  log likelihood = -92.053961
Iteration 1:  log likelihood = -90.164278
Iteration 2:  log likelihood = -90.125533
Iteration 3:  log likelihood = -90.125519
Iteration 4:  log likelihood = -90.125519
```

Multinomial logistic regression	Number of obs	=	99
	LR chi2(2)	=	3.86
	Prob > chi2	=	0.1454
Log likelihood = -90.125519	Pseudo R2	=	0.0209

withdrawal~e	Coef.	Std. Err.	z	P> z	[95% Conf. Interval]
0	(base outcome)				
1					
b_employmen~s					
Yes	0	(base)			
No	-.4626235	.5298439	-0.87	0.383	-1.501098 .5758514
_cons	-.8873032	.3175537	-2.79	0.005	-1.509697 -.2649094
2					
b_employmen~s					
Yes	0	(base)			
No	.8366595	.5692316	1.47	0.142	-.2790139 1.952333
_cons	-1.734601	.4428074	-3.92	0.000	-2.602488 -.8667144

```
. mlogit withdrawal_time i.job_status, base
```

```
Iteration 0:  log likelihood = -92.053961
Iteration 1:  log likelihood = -89.154727
Iteration 2:  log likelihood = -89.060936
Iteration 3:  log likelihood = -89.060734
```

Iteration 4: log likelihood = -89.060734

Multinomial logistic regression	Number of obs	=	99
	LR chi2(4)	=	5.99
	Prob > chi2	=	0.2002
Log likelihood = -89.060734	Pseudo R2	=	0.0325

withdrawal~e	Coef.	Std. Err.	z	P> z	[95% Conf. Interval]	
0	(base outcome)					
1						
job_status						
A_C1	0	(base)				
C2_E	1.024504	1.131063	0.91	0.365	-1.192339	3.241348
Unemployed	.4418328	1.160414	0.38	0.703	-1.832537	2.716203
_cons	-1.791759	1.080123	-1.66	0.097	-3.908763	.3252436
2						
job_status						
A_C1	0	(base)				
C2_E	-.8472979	.9759001	-0.87	0.385	-2.760027	1.065431
Unemployed	.2006707	.8914106	0.23	0.822	-1.546462	1.947803
_cons	-1.098612	.8164966	-1.35	0.178	-2.698916	.5016916

. mlogit withdrawal_time b_age_left_education, base

Iteration 0: log likelihood = -92.053961
Iteration 1: log likelihood = -90.375815
Iteration 2: log likelihood = -90.169975
Iteration 3: log likelihood = -90.169515
Iteration 4: log likelihood = -90.169515

Multinomial logistic regression	Number of obs	=	99
	LR chi2(2)	=	3.77
	Prob > chi2	=	0.1519
Log likelihood = -90.169515	Pseudo R2	=	0.0205

withdrawal~e	Coef.	Std. Err.	z	P> z	[95% Conf. Interval]	
0	(base outcome)					
1						
b_age_left~n	.0354993	.1219083	0.29	0.771	-.2034365	.2744352
_cons	-1.650241	2.02494	-0.81	0.415	-5.619051	2.318568
2						
b_age_left~n	-.4403987	.2909464	-1.51	0.130	-1.010643	.1298458
_cons	5.7333	4.580344	1.25	0.211	-3.24401	14.71061

. mlogit withdrawal_time i.b_smoke_cohabitants, base

Iteration 0: log likelihood = -92.053961
Iteration 1: log likelihood = -88.929719
Iteration 2: log likelihood = -88.766091
Iteration 3: log likelihood = -88.765542
Iteration 4: log likelihood = -88.765542

Multinomial logistic regression	Number of obs	=	99
	LR chi2(4)	=	6.58
	Prob > chi2	=	0.1600
Log likelihood = -88.765542	Pseudo R2	=	0.0357

withdrawal_~e		Coef.	Std. Err.	z	P> z	[95% Conf. Interval]	
0		(base outcome)					
1							
b_smoke_coh~s							
Yes		0	(base)				
No		1.730066	.7454602	2.32	0.020	.2689907	3.191141
NA		.8137752	.7363759	1.11	0.269	-.629495	2.257045
_cons		-1.99243	.6154575	-3.24	0.001	-3.198705	-.7861557
2							
b_smoke_coh~s							
Yes		0	(base)				
No		.120628	.7341964	0.16	0.869	-1.31837	1.559626
NA		-.0129034	.6272479	-0.02	0.984	-1.242287	1.21648
_cons		-1.299283	.4605662	-2.82	0.005	-2.201976	-.3965898

```
. mlogit withdrawal_time smoke_years, base
```

```
Iteration 0: log likelihood = -92.053961
Iteration 1: log likelihood = -88.124016
Iteration 2: log likelihood = -87.988462
Iteration 3: log likelihood = -87.9883
Iteration 4: log likelihood = -87.9883
```

Multinomial logistic regression	Number of obs	=	99
	LR chi2(2)	=	8.13
	Prob > chi2	=	0.0172
Log likelihood = -87.9883	Pseudo R2	=	0.0442

withdrawal~e		Coef.	Std. Err.	z	P> z	[95% Conf. Interval]	
0		(base outcome)					
1							
smoke_years		-.0542144	.0218263	-2.48	0.013	-.0969931	-.0114356
_cons		.5271403	.6595346	0.80	0.424	-.7655237	1.819804
2							
smoke_years		.0147022	.0246052	0.60	0.550	-.0335231	.0629276
_cons		-1.781165	.8990841	-1.98	0.048	-3.543337	-.0189924

```
. mlogit withdrawal_time i.qa24_pastyear, base
```

```
Iteration 0: log likelihood = -92.053961
Iteration 1: log likelihood = -90.868009
Iteration 2: log likelihood = -90.849447
Iteration 3: log likelihood = -90.849436
Iteration 4: log likelihood = -90.849436
```

Multinomial logistic regression	Number of obs	=	99
	LR chi2(2)	=	2.41
	Prob > chi2	=	0.2998
Log likelihood = -90.849436	Pseudo R2	=	0.0131

withdrawal_~e	Coef.	Std. Err.	z	P> z	[95% Conf. Interval]	
0	(base outcome)					
1						
qa24_pastyear						
0	0	(base)				
1	.4067818	.510591	0.80	0.426	-.5939582	1.407522

	_cons	-1.239691	.3423812	-3.62	0.000	-1.910746	-.5686361
2	qa24_pastyear						
	0		0 (base)				
	1	-.6765631	.6298548	-1.07	0.283	-1.911056	.5579298
	_cons	-1.072637	.3213081	-3.34	0.001	-1.702389	-.4428846

. mlogit withdrawal_time i.b_use_of_sss, base

Iteration 0: log likelihood = -92.053961
Iteration 1: log likelihood = -91.637435
Iteration 2: log likelihood = -91.63573
Iteration 3: log likelihood = -91.63573

Multinomial logistic regression	Number of obs	=	99
	LR chi2(2)	=	0.84
	Prob > chi2	=	0.6582
Log likelihood = -91.63573	Pseudo R2	=	0.0045

withdrawal~e	Coef.	Std. Err.	z	P> z	[95% Conf. Interval]	
<hr/>						
0	(base outcome)					
<hr/>						
1						
b_use_of_sss						
1	0	(base)				
2	.3958957	.5303948	0.75	0.455	-.6436591	1.43545
_cons	-1.312186	.4258153	-3.08	0.002	-2.146769	-.4776037
<hr/>						
2						
b_use_of_sss						
1	0	(base)				
2	-.1794685	.5505852	-0.33	0.744	-1.258596	.8996587
_cons	-1.178655	.4043038	-2.92	0.004	-1.971076	-.3862342

. mlogit withdrawal_time baselinecompositemecigs, base

Iteration 0: log likelihood = -92.053961
Iteration 1: log likelihood = -91.545572
Iteration 2: log likelihood = -91.52871
Iteration 3: log likelihood = -91.528691
Iteration 4: log likelihood = -91.528691

Multinomial logistic regression	Number of obs	=	99
	LR chi2(2)	=	1.05
	Prob > chi2	=	0.5914
Log likelihood = -91.528691	Pseudo R2	=	0.0057

withdrawal~e	Coef.	Std. Err.	z	P> z	[95% Conf. Interval]	
0	(base outcome)					
1						
baselinecom~s	-.0163006	.0219854	-0.74	0.458	-.0593911	.02679
_cons	-.7340018	.5014317	-1.46	0.143	-1.71679	.2487863
2						
baselinecom~s	.0080917	.0171299	0.47	0.637	-.0254823	.0416657
_cons	-1.461417	.4829641	-3.03	0.002	-2.408009	-.5148244

```
. mlogit withdrawal_time b_co_ppm, base
```

```
Iteration 0:  log likelihood = -90.267116
Iteration 1:  log likelihood = -88.411495
Iteration 2:  log likelihood = -88.336119
Iteration 3:  log likelihood = -88.33608
Iteration 4:  log likelihood = -88.33608
```

```
Multinomial logistic regression      Number of obs   =          98
                                      LR chi2(2)         =           3.86
                                      Prob > chi2        =          0.1450
Log likelihood = -88.33608           Pseudo R2       =          0.0214
```

withdrawal~e		Coef.	Std. Err.	z	P> z	[95% Conf. Interval]	
0		(base outcome)					
1							
	b_co_ppm	.0146425	.0331377	0.44	0.659	-.0503062	.0795913
	_cons	-1.322284	.6381065	-2.07	0.038	-2.57295	-.0716187
2							
	b_co_ppm	.0659865	.0338927	1.95	0.052	-.000442	.1324151
	_cons	-2.602997	.7419048	-3.51	0.000	-4.057104	-1.148891

```
. mlogit withdrawal_time i.typ_of_cig, base
```

```
Iteration 0:  log likelihood = -92.053961
Iteration 1:  log likelihood = -90.855533
Iteration 2:  log likelihood = -90.834301
Iteration 3:  log likelihood = -90.834251
Iteration 4:  log likelihood = -90.834251
```

```
Multinomial logistic regression      Number of obs   =          99
                                      LR chi2(4)         =           2.44
                                      Prob > chi2        =          0.6555
Log likelihood = -90.834251           Pseudo R2       =          0.0132
```

withdrawal~e		Coef.	Std. Err.	z	P> z	[95% Conf. Interval]	
0		(base outcome)					
1							
	typ_of_cig						
	1	0	(base)				
	2	.1098957	.5768157	0.19	0.849	-1.020642	1.240434
	3	-.6632942	.9035482	-0.73	0.463	-2.434216	1.107628
	_cons	-1.041454	.4748581	-2.19	0.028	-1.972159	-.1107491
2							
	typ_of_cig						
	1	0	(base)				
	2	-.1524686	.5964841	-0.26	0.798	-1.321556	1.016619
	3	-1.356441	1.147344	-1.18	0.237	-3.605195	.8923124
	_cons	-1.041454	.4748581	-2.19	0.028	-1.972159	-.1107491

```
. mlogit withdrawal_time ftnd_baseline, base
```

```
Iteration 0:  log likelihood = -92.053961
Iteration 1:  log likelihood = -90.222688
Iteration 2:  log likelihood = -90.188466
Iteration 3:  log likelihood = -90.188432
Iteration 4:  log likelihood = -90.188432
```

```

Multinomial logistic regression
Log likelihood = -90.188432
Number of obs   =      99
LR chi2(2)      =      3.73
Prob > chi2     =      0.1548
Pseudo R2      =      0.0203

```

withdrawal_~e	Coef.	Std. Err.	z	P> z	[95% Conf. Interval]	
0	(base outcome)					
1						
ftnd_baseline	.1001756	.1272824	0.79	0.431	-.1492933	.3496445
_cons	-1.618693	.7581328	-2.14	0.033	-3.104606	-.1327803
2						
ftnd_baseline	.2674687	.1459642	1.83	0.067	-.0186158	.5535533
_cons	-2.840122	.9376175	-3.03	0.002	-4.677819	-1.002426

```
. mlogit withdrawal_time i.b_import_quitHIGHLOW, base
```

```

Iteration 0:  log likelihood = -92.053961
Iteration 1:  log likelihood = -91.931984
Iteration 2:  log likelihood = -91.931964
Iteration 3:  log likelihood = -91.931964

```

```

Multinomial logistic regression
Log likelihood = -91.931964
Number of obs   =      99
LR chi2(2)      =      0.24
Prob > chi2     =      0.8852
Pseudo R2      =      0.0013

```

withdrawal_~e	Coef.	Std. Err.	z	P> z	[95% Conf. Interval]	
<hr/>						
0	(base outcome)					
<hr/>						
1						
b_import_qu~W						
1	0	(base)				
2	.1937503	.5065983	0.38	0.702	-.7991642	1.186665
_cons	-1.163151	.3622844	-3.21	0.001	-1.873215	-.4530864
<hr/>						
2						
b_import_qu~W						
1	0	(base)				
2	.2162231	.5494032	0.39	0.694	-.8605874	1.293034
_cons	-1.386294	.3952847	-3.51	0.000	-2.161038	-.6115506

```
. mlogit withdrawal_time i.b_import_quitHIGHLOW2, base
```

```

Iteration 0:  log likelihood = -92.053961
Iteration 1:  log likelihood = -90.40368
Iteration 2:  log likelihood = -90.400747
Iteration 3:  log likelihood = -90.400747

```

```

Multinomial logistic regression
Log likelihood = -90.400747
Number of obs   =      99
LR chi2(2)      =      3.31
Prob > chi2     =      0.1914
Pseudo R2      =      0.0180

```

withdrawal_~e	Coef.	Std. Err.	z	P> z	[95% Conf. Interval]
0	(base outcome)				
1					
b import qu~2					

1		0	(base)				
2		-.8329091	.5318367	-1.57	0.117	-1.87529	.2094716
_cons		-.5108256	.421637	-1.21	0.226	-1.337219	.3155678

2							
b_import_qu~2							
1		0	(base)				
2		-.7639163	.5755545	-1.33	0.184	-1.891982	.3641498
_cons		-.76214	.4577377	-1.67	0.096	-1.659289	.1350094

```
. mlogit withdrawal_time i.b_conf_quitHIGHLOW, base
```

```
Iteration 0:  log likelihood = -91.072658
Iteration 1:  log likelihood = -88.724872
Iteration 2:  log likelihood = -88.688757
Iteration 3:  log likelihood = -88.688719
Iteration 4:  log likelihood = -88.688719
```

Multinomial logistic regression	Number of obs	=	97
	LR chi2(2)	=	4.77
	Prob > chi2	=	0.0922
Log likelihood = -88.688719	Pseudo R2	=	0.0262

withdrawal~e	Coef.	Std. Err.	z	P> z	[95% Conf. Interval]	

0	(base outcome)					

1						
b_conf_quit~W						
1	0	(base)				
2	-.5951668	.5136694	-1.16	0.247	-1.60194	.4116067
_cons	-.7339692	.3511885	-2.09	0.037	-1.422286	-.0456524

2						
b_conf_quit~W						
1	0	(base)				
2	-1.182953	.5939235	-1.99	0.046	-2.347022	-.0188848
_cons	-.7339692	.3511885	-2.09	0.037	-1.422286	-.0456524

```
. mlogit withdrawal_time i.b_conf_quitHIGHLOW2, base
```

```
Iteration 0:  log likelihood = -91.072658
Iteration 1:  log likelihood = -87.898025
Iteration 2:  log likelihood = -87.867978
Iteration 3:  log likelihood = -87.86796
Iteration 4:  log likelihood = -87.86796
```

Multinomial logistic regression	Number of obs	=	97
	LR chi2(2)	=	6.41
	Prob > chi2	=	0.0406
Log likelihood = -87.86796	Pseudo R2	=	0.0352

withdrawal~e		Coef.	Std. Err.	z	P> z	[95% Conf. Interval]	

0		(base outcome)					

1							
b_conf_quit~2							
1		0	(base)				
2		-1.198696	.6803115	-1.76	0.078	-2.532082	.1346903
cons		-.7472144	.2861317	-2.61	0.009	-1.308022	-.1864066

```

-----+-----
2 |
b_conf_quit~2 |
      1 |          0 (base)
      2 | -1.421839   .8003759   -1.78   0.076   -2.990547   .1468685
      |
      _cons | -.929536   .3049302   -3.05   0.002   -1.527188   -.3318837
-----+-----

```

```
. mlogit withdrawal_time i.b_cut_halfHIGHLOW, base
```

```

Iteration 0:  log likelihood = -92.053961
Iteration 1:  log likelihood = -91.136842
Iteration 2:  log likelihood = -91.127637
Iteration 3:  log likelihood = -91.127636

```

```

Multinomial logistic regression              Number of obs   =          99
                                             LR chi2(2)         =           1.85
                                             Prob > chi2        =          0.3960
Log likelihood = -91.127636                 Pseudo R2         =          0.0101

```

```

-----+-----
withdrawal~e |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-----+-----
0 |      (base outcome)
-----+-----
1 |
b_cut_halfH~W |
      1 |          0 (base)
      2 |   .6678294   .5118639     1.30   0.192    -1.3354054    1.671064
      |
      _cons | -1.360977   .3544588    -3.84   0.000    -2.055703    -.6662501
-----+-----
2 |
b_cut_halfH~W |
      1 |          0 (base)
      2 |  -.0336166   .5732986    -0.06   0.953    -1.157261    1.090028
      |
      _cons | -1.265666   .3413944    -3.71   0.000    -1.934787    -.5965457
-----+-----

```

```
. mlogit withdrawal_time i.b_self_reported_pa_mod, base
```

```

Iteration 0:  log likelihood = -92.053961
Iteration 1:  log likelihood = -89.716715
Iteration 2:  log likelihood = -89.713185
Iteration 3:  log likelihood = -89.713184

```

```

Multinomial logistic regression              Number of obs   =          99
                                             LR chi2(2)         =           4.68
                                             Prob > chi2        =          0.0963
Log likelihood = -89.713184                 Pseudo R2         =          0.0254

```

```

-----+-----
withdrawal~e |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-----+-----
0 |      (base outcome)
-----+-----
1 |
b_self_repo~d |
      0 |          0 (base)
      1 | -1.126783   .6282587    -1.79   0.073    -2.358148    .1045812
      |
      _cons | -.1541507   .5563486    -0.28   0.782    -1.244574    .9362726
-----+-----
2 |
b_self_repo~d |
      0 |          0 (base)
      1 | -1.167605   .6668651    -1.75   0.080    -2.474637    .1394263
      |

```

```

      _cons |   -.3364722    .58554   -0.57   0.566   -1.48411   .8111652
-----+-----

. mlogit withdrawal_time b_modvig_day, base

Iteration 0:   log likelihood = -92.053961
Iteration 1:   log likelihood = -90.627164
Iteration 2:   log likelihood = -90.550641
Iteration 3:   log likelihood = -90.550293
Iteration 4:   log likelihood = -90.550293

Multinomial logistic regression              Number of obs   =          99
                                             LR chi2(2)        =           3.01
                                             Prob > chi2       =          0.2223
Log likelihood = -90.550293                 Pseudo R2        =          0.0163

-----+-----
withdrawal~e |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-----+-----
0              |   (base outcome)
-----+-----
1              |
b_modvig_day |   -.0010178   .0028054    -0.36   0.717    - .0065163    .0044807
   _cons      |   -.9884778   .3278213    -3.02   0.003    -1.630996    -.3459599
-----+-----
2              |
b_modvig_day |   -.0071801   .0049635    -1.45   0.148    - .0169084    .0025483
   _cons      |   -.8591301   .3626461    -2.37   0.018    -1.569903    -.1483567
-----+-----

. mlogit withdrawal_time B_accel, base

Iteration 0:   log likelihood = -62.569577
Iteration 1:   log likelihood = -61.868853
Iteration 2:   log likelihood = -61.831856
Iteration 3:   log likelihood = -61.831822
Iteration 4:   log likelihood = -61.831822

Multinomial logistic regression              Number of obs   =           66
                                             LR chi2(2)        =           1.48
                                             Prob > chi2       =          0.4782
Log likelihood = -61.831822                 Pseudo R2        =          0.0118

-----+-----
withdrawal~e |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-----+-----
0              |   (base outcome)
-----+-----
1              |
   B_accel    |   -.0032127   .0123714    -0.26   0.795    - .0274602    .0210347
   _cons      |   -.5963067   .4640446    -1.29   0.199    -1.505817    .3132041
-----+-----
2              |
   B_accel    |    .0150381   .013723     1.10   0.273    - .0118586    .0419348
   _cons      |   -1.978511   .6477867    -3.05   0.002    -3.248149    -.708872
-----+-----

. mlogit withdrawal_time i.soc_paHIGHLOW, base

Iteration 0:   log likelihood = -92.053961
Iteration 1:   log likelihood = -90.812437
Iteration 2:   log likelihood = -90.789522
Iteration 3:   log likelihood = -90.789494
Iteration 4:   log likelihood = -90.789494

Multinomial logistic regression              Number of obs   =           99
                                             LR chi2(2)        =           2.53
                                             Prob > chi2       =          0.2824
Log likelihood = -90.789494                 Pseudo R2        =          0.0137

```

withdrawal_~e	Coef.	Std. Err.	z	P> z	[95% Conf. Interval]	
0	(base outcome)					
1						
soc_paHIGHLOW						
1	0	(base)				
2	-1.130701	.8006481	-1.41	0.158	-2.699942	.4385408
_cons	-.8842024	.2727099	-3.24	0.001	-1.418704	-.3497008
2						
soc_paHIGHLOW						
1	0	(base)				
2	-.4198538	.702259	-0.60	0.550	-1.796256	.9565485
_cons	-1.189584	.3052338	-3.90	0.000	-1.787831	-.5913367

```
. mlogit withdrawal_time i.b_conf_ex30HIGHLOW, base
```

```
Iteration 0:  log likelihood = -92.053961
Iteration 1:  log likelihood = -91.756917
Iteration 2:  log likelihood = -91.755522
Iteration 3:  log likelihood = -91.755522
```

Multinomial logistic regression	Number of obs	=	99
	LR chi2(2)	=	0.60
	Prob > chi2	=	0.7420
Log likelihood = -91.755522	Pseudo R2	=	0.0032

withdrawal~e	Coef.	Std. Err.	z	P> z	[95% Conf. Interval]	
0	(base outcome)					
1						
b_conf_ex30~W						
1	0	(base)				
2	-.0095695	.5113486	-0.02	0.985	-1.011794	.9926554
_cons	-1.060872	.3867462	-2.74	0.006	-1.818881	-.3028633
2						
b_conf_ex30~W						
1	0	(base)				
2	-.4150346	.5505852	-0.75	0.451	-1.494162	.6640926
_cons	-1.060872	.3867462	-2.74	0.006	-1.818881	-.3028633

```
. mlogit withdrawal_time i.b_conf_walk15HIGHLOW, base
```

```
Iteration 0:  log likelihood = -92.053961
Iteration 1:  log likelihood = -91.930235
Iteration 2:  log likelihood = -91.930004
Iteration 3:  log likelihood = -91.930004
```

Multinomial logistic regression	Number of obs	=	99
	LR chi2(2)	=	0.25
	Prob > chi2	=	0.8834
Log likelihood = -91.930004	Pseudo R2	=	0.0013

withdrawal_e	Coef.	Std. Err.	z	P> z	[95% Conf. Interval]
0	(base outcome)				
1					


```

b_conf_walk~W |
      1 |          0 (base)
      2 |   -.076961   .5120764   -0.15   0.881   -1.080612   .9266902
      |
    _cons |  -1.021651   .3887301   -2.63   0.009   -1.783548   -.2597542
-----+-----
2
b_conf_walk~W |
      1 |          0 (base)
      2 |   .2414927   .5703977    0.42   0.672   -.8764663   1.359452
      |
    _cons |  -1.427116   .4546061   -3.14   0.002   -2.318128   -.5361049
-----+-----

```

```
. mlogit withdrawal_time i.mental_health_prob, base
```

```

Iteration 0:  log likelihood = -92.053961
Iteration 1:  log likelihood = -91.37194
Iteration 2:  log likelihood = -91.367588
Iteration 3:  log likelihood = -91.367587

```

```

Multinomial logistic regression          Number of obs   =          99
                                         LR chi2(2)        =           1.37
                                         Prob > chi2       =          0.5034
Log likelihood = -91.367587              Pseudo R2       =          0.0075

```

```

-----+-----
withdrawal~e |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-----+-----
0             |      (base outcome)
-----+-----
1
mental_heal~b |
      0 |          0 (base)
      1 |   .5974021   .510591    1.17   0.242   -.4033378   1.598142
      |
    _cons |  -1.335001   .3554093   -3.76   0.000   -2.031591   -.6384116
-----+-----
2
mental_heal~b |
      0 |          0 (base)
      1 |   .145417   .5591522    0.26   0.795   -.9505012   1.241335
      |
    _cons |  -1.335001   .3554093   -3.76   0.000   -2.031591   -.6384116
-----+-----

```

```
. mlogit withdrawal_time i.b_modvig_day_30, base
```

```

Iteration 0:  log likelihood = -92.053961
Iteration 1:  log likelihood = -90.519937
Iteration 2:  log likelihood = -90.512539
Iteration 3:  log likelihood = -90.512539

```

```

Multinomial logistic regression          Number of obs   =          99
                                         LR chi2(2)        =           3.08
                                         Prob > chi2       =          0.2141
Log likelihood = -90.512539              Pseudo R2       =          0.0167

```

```

-----+-----
withdrawal~e |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-----+-----
0             |      (base outcome)
-----+-----
1
b_modvig_d~30 |
      0 |          0 (base)
      1 |  -.8556661   .5219769   -1.64   0.101   -1.878722   .1673898
      |
    _cons |  -.5306282   .3985267   -1.33   0.183   -1.311726   .2504697
-----+-----

```

```

2
b_modvig_d~30 |
      0 |          0 (base)
      1 |   -.5943013   .5695682   -1.04   0.297   -1.710635   .5220318
      |
      _cons |   -.8873032   .4490887   -1.98   0.048   -1.767501   -.0071055
-----

```

```
. mlogit withdrawal_time i.b_30minmodvig_5days, base
```

```

Iteration 0:  log likelihood = -92.053961
Iteration 1:  log likelihood = -91.744795
Iteration 2:  log likelihood = -91.743518
Iteration 3:  log likelihood = -91.743518

```

```

Multinomial logistic regression              Number of obs   =          99
                                             LR chi2(2)         =           0.62
                                             Prob > chi2        =          0.7331
Log likelihood = -91.743518                 Pseudo R2         =          0.0034

```

```

-----
withdrawal_~e |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-----+-----
0              |      (base outcome)
-----+-----
1
b_30minmodv~s |
      0 |          0 (base)
      1 |   -.123379   .5103545    -0.24   0.809   -1.123656   .8768975
      |
      _cons |  -1.011601   .3370999    -3.00   0.003   -1.672305  -.3508972
-----+-----
2
b_30minmodv~s |
      0 |          0 (base)
      1 |  -.4418327   .5688524    -0.78   0.437   -1.556763   .6730975
      |
      _cons |  -1.098612   .3481553    -3.16   0.002   -1.780984  -.4162404
-----

```

```
. mlogit withdrawal_time i.b_accel_30mins_day, base
```

```

Iteration 0:  log likelihood = -62.569577
Iteration 1:  log likelihood = -61.816016
Iteration 2:  log likelihood = -61.799706
Iteration 3:  log likelihood = -61.799696
Iteration 4:  log likelihood = -61.799696

```

```

Multinomial logistic regression              Number of obs   =           66
                                             LR chi2(2)         =           1.54
                                             Prob > chi2        =          0.4631
Log likelihood = -61.799696                 Pseudo R2         =          0.0123

```

```

-----
withdrawal_~e |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-----+-----
0              |      (base outcome)
-----+-----
1
b_accel_30m~y |
      0 |          0 (base)
      1 |  -.2130932   .5669785    -0.38   0.707   -1.324351   .8981643
      |
      _cons |  -.597837   .3753786    -1.59   0.111   -1.333566   .1378915
-----+-----
2
b_accel_30m~y |
      0 |          0 (base)
      1 |   .7985077   .7781745     1.03   0.305   -.7266863   2.323702
      |

```

```

      _cons |   -1.89712   .6191392   -3.06   0.002   -3.11061   -.6836295
-----+-----

. mlogit withdrawal_time i.b_150mins_modvig_week, base

Iteration 0:   log likelihood = -92.053961
Iteration 1:   log likelihood = -88.995587
Iteration 2:   log likelihood = -88.977361
Iteration 3:   log likelihood = -88.977359

Multinomial logistic regression               Number of obs   =          99
                                                LR chi2(2)        =           6.15
                                                Prob > chi2       =          0.0461
Log likelihood = -88.977359                  Pseudo R2        =          0.0334

-----+-----
withdrawal_~e |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-----+-----
0              |      (base outcome)
-----+-----
1              |
b_150mins_m~k |
      0        |              0   (base)
      1        |   -1.210942   .537276     -2.25   0.024    -2.263983    -.1578999
      _cons    |   -.2623642   .4206222    -0.62   0.533    -1.086769    .5620403
-----+-----
2              |
b_150mins_m~k |
      0        |              0   (base)
      1        |   -.9495767   .5836211     -1.63   0.104    -2.093453    .1942996
      _cons    |   -.6190392   .4688072     -1.32   0.187    -1.537885    .2998061
-----+-----

.
. mlogit withdrawal_time i.rec_avenue2, base rrr

Iteration 0:   log likelihood = -92.053961
Iteration 1:   log likelihood = -91.901591
Iteration 2:   log likelihood = -91.901309
Iteration 3:   log likelihood = -91.901309

Multinomial logistic regression               Number of obs   =          99
                                                LR chi2(4)        =           0.31
                                                Prob > chi2       =          0.9895
Log likelihood = -91.901309                  Pseudo R2        =          0.0017

-----+-----
withdrawal_~e |      RRR   Std. Err.      z    P>|z|     [95% Conf. Interval]
-----+-----
0              |      (base outcome)
-----+-----
1              |
  rec_avenue2 |
Primary care   |              1   (base)
      SSS      |   .7928571   .4450763    -0.41   0.679    .2638557    2.382447
      Community |   .6607143   .7672414    -0.36   0.721    .0678536    6.433609
      _cons     |   .3783784   .1187262    -3.10   0.002    .2045688    .6998633
-----+-----
2              |
  rec_avenue2 |
Primary care   |              1   (base)
      SSS      |   .8409091   .5100764    -0.29   0.775    .2561117    2.761014
      Community |   .8409091   .9835172    -0.15   0.882    .084956    8.323465
      _cons     |   .2972973   .1020973    -3.53   0.000    .1516606    .582786
-----+-----

```

```
. mlogit withdrawal_time i.rec_method, base rrr
```

```
Iteration 0:  log likelihood = -92.053961
Iteration 1:  log likelihood = -89.78608
Iteration 2:  log likelihood = -89.736117
Iteration 3:  log likelihood = -89.736087
Iteration 4:  log likelihood = -89.736087
```

```
Multinomial logistic regression      Number of obs   =      99
                                      LR chi2(4)         =       4.64
                                      Prob > chi2        =     0.3268
Log likelihood = -89.736087          Pseudo R2       =     0.0252
```

withdrawal~e		RRR	Std. Err.	z	P> z	[95% Conf. Interval]	
0	(base outcome)						
1							
	rec_method						
	Letter	1	(base)				
	Phone	1.636364	.867377	0.93	0.353	.5790136	4.624565
	NA	.8636364	1.009836	-0.13	0.900	.0873041	8.54333
	_cons	.2894737	.0991103	-3.62	0.000	.14797	.5662973
2							
	rec_method						
	Letter	1	(base)				
	Phone	3.333333	1.959632	2.05	0.041	1.053092	10.55094
	NA	1.583333	1.901967	0.38	0.702	.1503396	16.67521
	_cons	.1578947	.0693628	-4.20	0.000	.0667478	.3735068

```
. mlogit withdrawal_time age_years, base rrr
```

```
Iteration 0:  log likelihood = -92.053961
Iteration 1:  log likelihood = -88.770219
Iteration 2:  log likelihood = -88.669273
Iteration 3:  log likelihood = -88.669168
Iteration 4:  log likelihood = -88.669168
```

```
Multinomial logistic regression      Number of obs   =      99
                                      LR chi2(2)         =       6.77
                                      Prob > chi2        =     0.0339
Log likelihood = -88.669168          Pseudo R2       =     0.0368
```

withdrawal~e		RRR	Std. Err.	z	P> z	[95% Conf. Interval]	
0	(base outcome)						
1							
	age_years	.9442207	.0222778	-2.43	0.015	.9015513	.9889097
	_cons	4.446818	4.664674	1.42	0.155	.5690446	34.74981
2							
	age_years	1.001099	.0255964	0.04	0.966	.9521668	1.052545
	_cons	.2643309	.3337799	-1.05	0.292	.0222488	3.140435

```
. mlogit withdrawal_time i.b_gender, base rrr
```

```
Iteration 0:  log likelihood = -92.053961
Iteration 1:  log likelihood = -91.489714
Iteration 2:  log likelihood = -91.488893
Iteration 3:  log likelihood = -91.488893
```

```
Multinomial logistic regression      Number of obs   =      99
```

```

Log likelihood = -91.488893
LR chi2(2)      =      1.13
Prob > chi2     =      0.5683
Pseudo R2      =      0.0061

```

withdrawal~e		RRR	Std. Err.	z	P> z	[95% Conf. Interval]	
0	(base outcome)						
1							
	b_gender						
	Male	1	(base)				
	Female	1.472656	.7618856	0.75	0.454	.53423	4.059518
	_cons	.2758621	.1101663	-3.22	0.001	.1261137	.6034229
2							
	b_gender						
	Male	1	(base)				
	Female	1.661458	.9447089	0.89	0.372	.5451228	5.063894
	_cons	.2068966	.0927925	-3.51	0.000	.0858998	.4983271

```
. mlogit withdrawal_time bmi_baseline, base rrr
```

```

Iteration 0:  log likelihood = -91.566541
Iteration 1:  log likelihood = -91.299574
Iteration 2:  log likelihood = -91.298481
Iteration 3:  log likelihood = -91.298481

```

```

Multinomial logistic regression
Log likelihood = -91.298481
Number of obs   =      98
LR chi2(2)      =      0.54
Prob > chi2     =      0.7649
Pseudo R2      =      0.0029

```

withdrawal~e		RRR	Std. Err.	z	P> z	[95% Conf. Interval]	
0	(base outcome)						
1							
	bmi_baseline	1.023041	.0394011	0.59	0.554	.948659	1.103255
	_cons	.1829081	.2074616	-1.50	0.134	.0198046	1.68927
2							
	bmi_baseline	.9873151	.0447486	-0.28	0.778	.9033922	1.079034
	_cons	.4039113	.5179837	-0.71	0.480	.0327106	4.987505

```
. mlogit withdrawal_time i.b_employment_status, base rrr
```

```

Iteration 0:  log likelihood = -92.053961
Iteration 1:  log likelihood = -90.164278
Iteration 2:  log likelihood = -90.125533
Iteration 3:  log likelihood = -90.125519
Iteration 4:  log likelihood = -90.125519

```

```

Multinomial logistic regression
Log likelihood = -90.125519
Number of obs   =      99
LR chi2(2)      =      3.86
Prob > chi2     =      0.1454
Pseudo R2      =      0.0209

```

withdrawal~e		RRR	Std. Err.	z	P> z	[95% Conf. Interval]	
0	(base outcome)						
1							
	b_employemen~s						

Yes		1 (base)					
No		.6296296	.3336054	-0.87	0.383	.2228852	1.778644
_cons		.4117647	.1307574	-2.79	0.005	.2209769	.7672754

2							
b_employen~s							
Yes		1 (base)					
No		2.308642	1.314152	1.47	0.142	.7565294	7.045103
_cons		.1764706	.0781425	-3.92	0.000	.074089	.4203303

```
. mlogit withdrawal_time i.job_status, base rrr
```

```
Iteration 0:  log likelihood = -92.053961
Iteration 1:  log likelihood = -89.154727
Iteration 2:  log likelihood = -89.060936
Iteration 3:  log likelihood = -89.060734
Iteration 4:  log likelihood = -89.060734
```

Multinomial logistic regression	Number of obs	=	99
	LR chi2(4)	=	5.99
	Prob > chi2	=	0.2002
Log likelihood = -89.060734	Pseudo R2	=	0.0325

withdrawal~e		RRR	Std. Err.	z	P> z	[95% Conf. Interval]	

0		(base outcome)					

1							
job_status							
A_C1		1	(base)				
C2_E		2.785714	3.150819	0.91	0.365	.3035106	25.56815
Unemployed		1.555556	1.805089	0.38	0.703	.1600071	15.12279
_cons		.1666667	.1800206	-1.66	0.097	.0200653	1.384368

2							
job_status							
A_C1		1	(base)				
C2_E		.4285714	.4182429	-0.87	0.385	.0632901	2.90209
Unemployed		1.222222	1.089502	0.23	0.822	.2130003	7.013265
_cons		.3333333	.2721655	-1.35	0.178	.0672784	1.651513

```
. mlogit withdrawal_time b_age_left_education, base rrr
```

```
Iteration 0:  log likelihood = -92.053961
Iteration 1:  log likelihood = -90.375815
Iteration 2:  log likelihood = -90.169975
Iteration 3:  log likelihood = -90.169515
Iteration 4:  log likelihood = -90.169515
```

Multinomial logistic regression	Number of obs	=	99
	LR chi2(2)	=	3.77
	Prob > chi2	=	0.1519
Log likelihood = -90.169515	Pseudo R2	=	0.0205

withdrawal~e	RRR	Std. Err.	z	P> z	[95% Conf. Interval]	
0	(base outcome)					
1						
b_age_left~n	1.036137	.1263137	0.29	0.771	.815922	1.315787
_cons	.1920036	.3887957	-0.81	0.415	.0036281	10.16112

```

2
b_age_left~n | .6437797 .1873054 -1.51 0.130 .3639848 1.138653
_cons | 308.9873 1415.268 1.25 0.211 .0390072 2447580
-----

```

```
. mlogit withdrawal_time i.b_smoke_cohabitants, base rrr
```

```

Iteration 0: log likelihood = -92.053961
Iteration 1: log likelihood = -88.929719
Iteration 2: log likelihood = -88.766091
Iteration 3: log likelihood = -88.765542
Iteration 4: log likelihood = -88.765542

```

```

Multinomial logistic regression      Number of obs   =      99
                                      LR chi2(4)         =       6.58
                                      Prob > chi2        =     0.1600
Log likelihood = -88.765542          Pseudo R2       =     0.0357

```

```

-----
withdrawal~e |          RRR   Std. Err.      z    P>|z|     [95% Conf. Interval]
-----+-----
0              | (base outcome)
-----+-----
1              |
b_smoke_coh~s |
  Yes          |          1 (base)
  No           |  5.641026   4.20516     2.32   0.020   1.308643   24.31616
  NA           |  2.25641   1.661566    1.11   0.269   .5328608   9.554816
  _cons        |  .1363636   .083926   -3.24   0.001   .040815   .4555929
-----+-----
2              |
b_smoke_coh~s |
  Yes          |          1 (base)
  No           |  1.128205   .8283241    0.16   0.869   .267571   4.757044
  NA           |  .9871795   .6192062   -0.02   0.984   .2887233   3.375285
  _cons        |  .2727273   .125609   -2.82   0.005   .1105844   .6726098
-----

```

```
. mlogit withdrawal_time smoke_years, base rrr
```

```

Iteration 0: log likelihood = -92.053961
Iteration 1: log likelihood = -88.124016
Iteration 2: log likelihood = -87.988462
Iteration 3: log likelihood = -87.9883
Iteration 4: log likelihood = -87.9883

```

```

Multinomial logistic regression      Number of obs   =      99
                                      LR chi2(2)         =       8.13
                                      Prob > chi2        =     0.0172
Log likelihood = -87.9883          Pseudo R2       =     0.0442

```

```

-----
withdrawal~e |          RRR   Std. Err.      z    P>|z|     [95% Conf. Interval]
-----+-----
0              | (base outcome)
-----+-----
1              |
smoke_years   |  .947229   .0206745   -2.48   0.013   .9075622   .9886295
_cons         |  1.694081   1.117305    0.80   0.424   .4650903   6.170651
-----+-----
2              |
smoke_years   |  1.014811   .0249697    0.60   0.550   .9670326   1.06495
_cons         |  .1684418   .1514434   -1.98   0.048   .0289167   .9811868
-----

```

```
. mlogit withdrawal_time i.qa24_pastyear, base rrr
```

```
Iteration 0: log likelihood = -92.053961
```

```

Iteration 1:  log likelihood = -90.868009
Iteration 2:  log likelihood = -90.849447
Iteration 3:  log likelihood = -90.849436
Iteration 4:  log likelihood = -90.849436

```

```

Multinomial logistic regression      Number of obs   =          99
                                     LR chi2(2)         =           2.41
                                     Prob > chi2        =          0.2998
Log likelihood = -90.849436          Pseudo R2       =          0.0131

```

withdrawal_e	RRR	Std. Err.	z	P> z	[95% Conf. Interval]	
0	(base outcome)					
1						
qa24_pastyear						
0	1	(base)				
1	1.501976	.7668955	0.80	0.426	.5521375	4.085817
_cons	.2894737	.0991103	-3.62	0.000	.14797	.5662973
2						
qa24_pastyear						
0	1	(base)				
1	.5083612	.3201938	-1.07	0.283	.1479241	1.747052
_cons	.3421053	.1099212	-3.34	0.001	.1822476	.6421813

```
. mlogit withdrawal_time i.b_use_of_sss, base rrr
```

```

Iteration 0:  log likelihood = -92.053961
Iteration 1:  log likelihood = -91.637435
Iteration 2:  log likelihood = -91.63573
Iteration 3:  log likelihood = -91.63573

```

```

Multinomial logistic regression      Number of obs   =          99
                                     LR chi2(2)         =           0.84
                                     Prob > chi2        =          0.6582
Log likelihood = -91.63573          Pseudo R2       =          0.0045

```

withdrawal~e	RRR	Std. Err.	z	P> z	[95% Conf. Interval]	
0	(base outcome)					
1						
b_use_of_sss						
1	1	(base)				
2	1.485714	.7880152	0.75	0.455	.5253665	4.201537
_cons	.2692308	.1146426	-3.08	0.002	.1168611	.620268
2						
b_use_of_sss						
1	1	(base)				
2	.8357143	.4601319	-0.33	0.744	.2840526	2.458764
_cons	.3076923	.1244012	-2.92	0.004	.1393069	.6796114

```
. mlogit withdrawal_time baselinecompositemcigs, base rrr
```

```

Iteration 0:  log likelihood = -92.053961
Iteration 1:  log likelihood = -91.545572
Iteration 2:  log likelihood = -91.52871
Iteration 3:  log likelihood = -91.528691
Iteration 4:  log likelihood = -91.528691

```



```

Multinomial logistic regression
Log likelihood = -91.528691
Number of obs   =          99
LR chi2(2)      =          1.05
Prob > chi2     =          0.5914
Pseudo R2      =          0.0057

```

withdrawal_~e	RRR	Std. Err.	z	P> z	[95% Conf. Interval]	
0	(base outcome)					
1						
baselinecom~s	.9838316	.0216299	-0.74	0.458	.9423381	1.027152
_cons	.4799844	.2406794	-1.46	0.143	.1796419	1.282468
2						
baselinecom~s	1.008125	.0172691	0.47	0.637	.9748396	1.042546
_cons	.2319075	.112003	-3.03	0.002	.0899943	.5976055

```
. mlogit withdrawal_time b_co_ppm, base rrr
```

```

Iteration 0:  log likelihood = -90.267116
Iteration 1:  log likelihood = -88.411495
Iteration 2:  log likelihood = -88.336119
Iteration 3:  log likelihood = -88.33608
Iteration 4:  log likelihood = -88.33608

```

```

Multinomial logistic regression
Log likelihood = -88.33608
Number of obs   =          98
LR chi2(2)      =          3.86
Prob > chi2     =          0.1450
Pseudo R2      =          0.0214

```

withdrawal~e	RRR	Std. Err.	z	P> z	[95% Conf. Interval]	
0	(base outcome)					
1						
b_co_ppm	1.01475	.0336265	0.44	0.659	.9509382	1.082844
_cons	.2665258	.1700718	-2.07	0.038	.0763101	.9308857
2						
b_co_ppm	1.068212	.0362046	1.95	0.052	.9995581	1.141582
_cons	.0740513	.054939	-3.51	0.000	.017299	.3169882

```
. mlogit withdrawal_time i.typ_of_cig, base rrr
```

```

Iteration 0:  log likelihood = -92.053961
Iteration 1:  log likelihood = -90.855533
Iteration 2:  log likelihood = -90.834301
Iteration 3:  log likelihood = -90.834251
Iteration 4:  log likelihood = -90.834251

```

```

Multinomial logistic regression
Log likelihood = -90.834251
Number of obs   =          99
LR chi2(4)      =          2.44
Prob > chi2     =          0.6555
Pseudo R2      =          0.0132

```

withdrawal~e	RRR	Std. Err.	z	P> z	[95% Conf. Interval]	
0	(base outcome)					
1						
typ_of_cig						
1	1	(base)				
2	1.116162	.6438195	0.19	0.849	.3603634	3.457112
3	.5151515	.4654642	-0.73	0.463	.0876664	3.027168

	_cons		.3529412	.167597	-2.19	0.028	.1391561	.8951633
2								
	typ_of_cig							
	1		1	(base)				
	2		.8585859	.5121328	-0.26	0.798	.26672	2.763834
	3		.2575758	.2955281	-1.18	0.237	.0271821	2.440767
	_cons		.3529412	.167597	-2.19	0.028	.1391561	.8951633

. mlogit withdrawal_time ftnd_baseline, base rrr

Iteration 0: log likelihood = -92.053961
Iteration 1: log likelihood = -90.222688
Iteration 2: log likelihood = -90.188466
Iteration 3: log likelihood = -90.188432
Iteration 4: log likelihood = -90.188432

Multinomial logistic regression	Number of obs	=	99
	LR chi2(2)	=	3.73
	Prob > chi2	=	0.1548
Log likelihood = -90.188432	Pseudo R2	=	0.0203

withdrawal_~e		RRR	Std. Err.	z	P> z	[95% Conf. Interval]	
0		(base outcome)					
1							
ftnd_baseline		1.105365	.1406935	0.79	0.431	.8613164	1.418563
_cons		.1981575	.1502297	-2.14	0.033	.0448422	.8756575
2							
ftnd_baseline		1.306653	.1907245	1.83	0.067	.9815564	1.739423
_cons		.0584185	.0547742	-3.03	0.002	.0092993	.3669881

. mlogit withdrawal_time i.b_import_quitHIGHLOW, base rrr

Iteration 0: log likelihood = -92.053961
Iteration 1: log likelihood = -91.931984
Iteration 2: log likelihood = -91.931964
Iteration 3: log likelihood = -91.931964

Multinomial logistic regression	Number of obs	=	99
	LR chi2(2)	=	0.24
	Prob > chi2	=	0.8852
Log likelihood = -91.931964	Pseudo R2	=	0.0013

withdrawal_~e		RRR	Std. Err.	z	P> z	[95% Conf. Interval]	
0		(base outcome)					
1							
b_import_qu~W							
1		1	(base)				
2		1.213793	.6149055	0.38	0.702	.4497047	3.276136
_cons		.3125	.1132139	-3.21	0.001	.1536289	.6356632
2							
b_import_qu~W							
1		1	(base)				
2		1.241379	.6820178	0.39	0.694	.4229136	3.643824
_cons		.25	.0988212	-3.51	0.000	.1152054	.542509

```
. mlogit withdrawal_time i.b_import_quitHIGHLOW2, base rrr
```

```
Iteration 0:  log likelihood = -92.053961
Iteration 1:  log likelihood = -90.40368
Iteration 2:  log likelihood = -90.400747
Iteration 3:  log likelihood = -90.400747
```

```
Multinomial logistic regression      Number of obs   =          99
                                      LR chi2(2)         =           3.31
                                      Prob > chi2        =          0.1914
Log likelihood = -90.400747          Pseudo R2       =          0.0180
```

withdrawal_e	RRR	Std. Err.	z	P> z	[95% Conf. Interval]	
0	(base outcome)					
1						
b_import_qu~2						
1	1	(base)				
2	.4347826	.2312333	-1.57	0.117	.1533105	1.233026
_cons	.6	.2529822	-1.21	0.226	.2625749	1.371038
2						
b_import_qu~2						
1	1	(base)				
2	.4658385	.2681154	-1.33	0.184	.1507726	1.43929
_cons	.4666667	.2136109	-1.67	0.096	.1902741	1.144548

```
. mlogit withdrawal_time i.b_conf_quitHIGHLOW, base rrr
```

```
Iteration 0:  log likelihood = -91.072658
Iteration 1:  log likelihood = -88.724872
Iteration 2:  log likelihood = -88.688757
Iteration 3:  log likelihood = -88.688719
Iteration 4:  log likelihood = -88.688719
```

```
Multinomial logistic regression      Number of obs   =          97
                                      LR chi2(2)         =           4.77
                                      Prob > chi2        =          0.0922
Log likelihood = -88.688719          Pseudo R2       =          0.0262
```

withdrawal~e	RRR	Std. Err.	z	P> z	[95% Conf. Interval]	
0	(base outcome)					
1						
b_conf_quit~W						
1	1	(base)				
2	.5514706	.2832735	-1.16	0.247	.2015052	1.509241
_cons	.48	.1685705	-2.09	0.037	.2411621	.9553739
2						
b_conf_quit~W						
1	1	(base)				
2	.3063725	.1819618	-1.99	0.046	.0956536	.9812924
_cons	.48	.1685705	-2.09	0.037	.2411621	.9553739

```
. mlogit withdrawal_time i.b_conf_quitHIGHLOW2, base rrr
```

```
Iteration 0:  log likelihood = -91.072658
Iteration 1:  log likelihood = -87.898025
Iteration 2:  log likelihood = -87.867978
```

Iteration 3: log likelihood = -87.86796
 Iteration 4: log likelihood = -87.86796

Multinomial logistic regression	Number of obs	=	97
	LR chi2(2)	=	6.41
	Prob > chi2	=	0.0406
Log likelihood = -87.86796	Pseudo R2	=	0.0352

withdrawal~e	RRR	Std. Err.	z	P> z	[95% Conf. Interval]	
0	(base outcome)					
1						
b_conf_quit~2						
1	1	(base)				
2	.3015873	.2051733	-1.76	0.078	.0794934	1.144182
_cons	.4736842	.1355361	-2.61	0.009	.2703542	.8299361
2						
b_conf_quit~2						
1	1	(base)				
2	.2412698	.1931066	-1.78	0.076	.0502599	1.158202
_cons	.3947368	.1203672	-3.05	0.002	.2171454	.7175708

. mlogit withdrawal_time i.b_cut_halfHIGHLOW, base rrr

Iteration 0: log likelihood = -92.053961
 Iteration 1: log likelihood = -91.136842
 Iteration 2: log likelihood = -91.127637
 Iteration 3: log likelihood = -91.127636

Multinomial logistic regression	Number of obs	=	99
	LR chi2(2)	=	1.85
	Prob > chi2	=	0.3960
Log likelihood = -91.127636	Pseudo R2	=	0.0101

withdrawal~e	RRR	Std. Err.	z	P> z	[95% Conf. Interval]	
0	(base outcome)					
1						
b_cut_halfH~W						
1	1	(base)				
2	1.95	.9981346	1.30	0.192	.7150481	5.317824
_cons	.2564103	.0908869	-3.84	0.000	.1280028	.513631
2						
b_cut_halfH~W						
1	1	(base)				
2	.9669422	.5543466	-0.06	0.953	.3143459	2.974358
_cons	.2820513	.0962907	-3.71	0.000	.144455	.5507107

. mlogit withdrawal_time i.b_self_reported_pa_mod, base rrr

Iteration 0: log likelihood = -92.053961
 Iteration 1: log likelihood = -89.716715
 Iteration 2: log likelihood = -89.713185
 Iteration 3: log likelihood = -89.713184

Multinomial logistic regression	Number of obs	=	99
	LR chi2(2)	=	4.68
	Prob > chi2	=	0.0963

Pseudo R2 = 0.0254

withdrawal_time	RRR	Std. Err.	z	P> z	[95% Conf. Interval]	
0	(base outcome)					
1						
b_self_reported						
0	1	(base)				
1	.3240741	.2036024	-1.79	0.073	.0945953	1.110246
_cons	.8571429	.4768703	-0.28	0.782	.2880636	2.550457
2						
b_self_reported						
0	1	(base)				
1	.3111111	.2074691	-1.75	0.080	.0841936	1.149614
_cons	.7142857	.4182429	-0.57	0.566	.2267041	2.250529

```
. mlogit withdrawal_time b_modvig_day, base rrr
```

```
Iteration 0: log likelihood = -92.053961
Iteration 1: log likelihood = -90.627164
Iteration 2: log likelihood = -90.550641
Iteration 3: log likelihood = -90.550293
Iteration 4: log likelihood = -90.550293
```

Multinomial logistic regression

```
Number of obs    =          99
LR chi2(2)       =          3.01
Prob > chi2      =          0.2223
Pseudo R2       =          0.0163
```

Log likelihood = -90.550293

withdrawal~e	RRR	Std. Err.	z	P> z	[95% Conf. Interval]	
0	(base outcome)					
1						
b_modvig_day	.9989827	.0028026	-0.36	0.717	.9935049	1.004491
_cons	.3721427	.1219963	-3.02	0.003	.1957346	.7075409
2						
b_modvig_day	.9928456	.004928	-1.45	0.148	.9832337	1.002552
_cons	.4235304	.1535916	-2.37	0.018	.2080653	.8621235

```
. mlogit withdrawal time B accel, base rrr
```

```
Iteration 0: log likelihood = -62.569577
Iteration 1: log likelihood = -61.868853
Iteration 2: log likelihood = -61.831856
Iteration 3: log likelihood = -61.831822
Iteration 4: log likelihood = -61.831822
```

Multinomial logistic regression

```
Number of obs   =          66
LR chi2(2)      =          1.48
Prob > chi2     =          0.4782
Pseudo R2      =          0.0118
```

Log likelihood = -61.831822

withdrawal~e	RRR	Std. Err.	z	P> z	[95% Conf. Interval]	
0	(base outcome)					
1						
B_accel	.9967924	.0123317	-0.26	0.795	.9729134	1.021257
cons	.5508423	.2556154	-1.29	0.199	.2218359	1.367801

2							
B_accel		1.015152	.013931	1.10	0.273	.9882115	1.042826
_cons		.138275	.0895727	-3.05	0.002	.038846	.4921991

. mlogit withdrawal_time i.soc_paHIGHLOW, base rrr

Iteration 0: log likelihood = -92.053961
Iteration 1: log likelihood = -90.812437
Iteration 2: log likelihood = -90.789522
Iteration 3: log likelihood = -90.789494
Iteration 4: log likelihood = -90.789494

Multinomial logistic regression	Number of obs	=	99
	LR chi2(2)	=	2.53
	Prob > chi2	=	0.2824
Log likelihood = -90.789494	Pseudo R2	=	0.0137

withdrawal_~e		RRR	Std. Err.	z	P> z	[95% Conf. Interval]
0		(base outcome)				
1						
soc_paHIGHLOW						
1		1 (base)				
2		.322807	.2584548	-1.41	0.158	.0672094 1.550443
_cons		.4130435	.1126411	-3.24	0.001	.2420275 .704899
2						
soc_paHIGHLOW						
1		1 (base)				
2		.6571429	.4614845	-0.60	0.550	.1659189 2.602698
_cons		.3043478	.0928973	-3.90	0.000	.1673226 .5535868

. mlogit withdrawal_time i.b_conf_ex30HIGHLOW, base rrr

Iteration 0: log likelihood = -92.053961
Iteration 1: log likelihood = -91.756917
Iteration 2: log likelihood = -91.755522
Iteration 3: log likelihood = -91.755522

Multinomial logistic regression	Number of obs	=	99
	LR chi2(2)	=	0.60
	Prob > chi2	=	0.7420
Log likelihood = -91.755522	Pseudo R2	=	0.0032

withdrawal_~e		RRR	Std. Err.	z	P> z	[95% Conf. Interval]
0		(base outcome)				
1						
b_conf_ex30~W						
1		1 (base)				
2		.9904762	.5064786	-0.02	0.985	.363566 2.69839
_cons		.3461538	.1338737	-2.74	0.006	.1622072 .7387001
2						
b_conf_ex30~W						
1		1 (base)				
2		.6603175	.363561	-0.75	0.451	.2244367 1.942727
_cons		.3461538	.1338737	-2.74	0.006	.1622072 .7387001

```
. mlogit withdrawal_time i.b_conf_walk15HIGHLOW, base rrr
```

```
Iteration 0:  log likelihood = -92.053961
Iteration 1:  log likelihood = -91.930235
Iteration 2:  log likelihood = -91.930004
Iteration 3:  log likelihood = -91.930004
```

```
Multinomial logistic regression      Number of obs   =      99
                                      LR chi2(2)         =       0.25
                                      Prob > chi2        =     0.8834
Log likelihood = -91.930004          Pseudo R2       =     0.0013
```

withdrawal~e	RRR	Std. Err.	z	P> z	[95% Conf. Interval]	
0	(base outcome)					
1						
b_conf_walk~W						
1	1	(base)				
2	.9259259	.4741448	-0.15	0.881	.3393877	2.526134
_cons	.36	.1399428	-2.63	0.009	.1680408	.7712411
2						
b_conf_walk~W						
1	1	(base)				
2	1.273148	.7262008	0.42	0.672	.4162512	3.894057
_cons	.24	.1091055	-3.14	0.002	.0984577	.5850226

```
. mlogit withdrawal_time i.mental_health_prob, base rrr
```

```
Iteration 0:  log likelihood = -92.053961
Iteration 1:  log likelihood = -91.37194
Iteration 2:  log likelihood = -91.367588
Iteration 3:  log likelihood = -91.367587
```

```
Multinomial logistic regression      Number of obs   =      99
                                      LR chi2(2)         =       1.37
                                      Prob > chi2        =     0.5034
Log likelihood = -91.367587          Pseudo R2       =     0.0075
```

withdrawal~e		RRR	Std. Err.	z	P> z	[95% Conf. Interval]	
0		(base outcome)					
1							
mental_heal~b							
0		1	(base)				
1		1.817391	.9279436	1.17	0.242	.6680864	4.943838
_cons		.2631579	.0935288	-3.76	0.000	.1311268	.5281306
2							
mental_heal~b							
0		1	(base)				
1		1.156522	.6466717	0.26	0.795	.3865472	3.46023
_cons		.2631579	.0935288	-3.76	0.000	.1311268	.5281306

```
.
. tab withdrawal_time rec_avenue2
```

```
withdrawal |      1=PC, 2=SSS, 3=Community
_time | Primary c      SSS  Community |      Total
```

0	37	20	4	61
1	14	6	1	21
2	11	5	1	17
Total	62	31	6	99

```
. tab withdrawal_time rec_method
```

Recruitment Method (1=Letter, 2=Phonecall, 3=N/A)				
withdrawal_time	Letter	Phone	NA	Total
0	38	19	4	61
1	11	9	1	21
2	6	10	1	17
Total	55	38	6	99

```
. tab withdrawal_time age_years
```

too many values

```
r(134);
```

end of do-file

```
r(134);
```

```
. do "C:\Users\Tommy\AppData\Local\Temp\STD000000000.tmp"
```

```
. mlogit withdrawal_time i.b_conf_quitHIGHLOW i.b_150mins_modvig_week i.rec_meth
> od age_years smoke_years, base
```

```
Iteration 0: log likelihood = -91.072658
Iteration 1: log likelihood = -78.780883
Iteration 2: log likelihood = -78.101087
Iteration 3: log likelihood = -78.09854
Iteration 4: log likelihood = -78.09854
```

```
Multinomial logistic regression      Number of obs   =      97
                                      LR chi2(12)        =     25.95
                                      Prob > chi2         =     0.0109
Log likelihood = -78.09854           Pseudo R2        =     0.1425
```

withdrawal_time	Coef.	Std. Err.	z	P> z	[95% Conf. Interval]	
0	(base outcome)					
1						
b_conf_quit~W						
1	0	(base)				
2	-.6999056	.5655572	-1.24	0.216	-1.808377	.4085661
b_150mins_m~k						
0	0	(base)				
1	-1.470214	.6045149	-2.43	0.015	-2.655042	-.285387
rec_method						
Letter	0	(base)				
Phone	.2227735	.5954994	0.37	0.708	-.944384	1.389931
NA	-.6748831	1.274873	-0.53	0.597	-3.173588	1.823822
age_years	-.0000364	.0822671	-0.00	1.000	-.1612769	.161204
smoke_years	-.0565027	.0758604	-0.74	0.456	-.2051865	.092181
_cons	1.879955	1.815852	1.04	0.301	-1.679051	5.43896
2						
b_conf_quit~W						

1		0	(base)				
2		-.9915302	.6281087	-1.58	0.114	-2.222601	.2395402
b_150mins_m~k							
0		0	(base)				
1		-.6625232	.6627671	-1.00	0.317	-1.961523	.6364764
rec_method							
Letter		0	(base)				
Phone		1.023768	.6415844	1.60	0.111	-.2337141	2.281251
NA		.5373323	1.28561	0.42	0.676	-1.982418	3.057082
age_years		-.1825962	.1258485	-1.45	0.147	-.4292547	.0640623
smoke_years		.1889914	.121763	1.55	0.121	-.0496598	.4276425
_cons		1.498218	2.322951	0.64	0.519	-3.054682	6.051117

.
 end of do-file

.

Appendix 3 STATA commands, model and output for multiple imputation chained equations analyses

```
. do "C:\Users\Tommy\AppData\Local\Temp\STD00000000.tmp"

. capture

. mi set flong

. mi query
data mi set flong, M = 0
last mi update 23jun2015 21:15:43, 0 seconds ago

. mi register imputed CO_reduction_wk16_25_completers ///
> w16_reduction_50_completers wk4_co_quit_completers ///
> b_confquithigh_1 b_co_ppm
(40 m=0 obs. now marked as incomplete)

.
. mi register regular arm2 baselinecompositemcigs ///
> smoke_years ftnd_baseline b_gender age_years b_150mins_modvig_week ///
> rec_method HT2 mental_health_prob

.
. set seed 29390

.
. mi impute chained (logit, augment) wk4_co_quit_completers (logit, augment) //
> /
> CO_reduction_wk16_25_completers (pmm) b_co_ppm (logit, augment) ///
> w16_reduction_50_completers (logit, augment) b_confquithigh_1 ///
> = arm2 b_gender ///
> age_years i.HT2 ftnd_baseline baselinecompositemcigs b_150mins_modvig_week ///
> rec_method mental_health_prob , ///
> add (40) force report chaindots burnin(10) savetrace(extrace, replace)
```

Checking equations:

```
-- above applies to specification (pmm ) b_co_ppm = arm2 b_gender age_years
i.HT2 ftnd_baseline baselinecompositemcigs b_150mins_modvig_week rec_method
mental_health_prob

-- above applies to specification (logit , augment) b_confquithigh_1 = arm2
b_gender age_years i.HT2 ftnd_baseline baselinecompositemcigs
b_150mins_modvig_week rec_method mental_health_prob

-- above applies to specification (logit , augment) wk4_co_quit_completers =
arm2 b_gender age_years i.HT2 ftnd_baseline baselinecompositemcigs
b_150mins_modvig_week rec_method mental_health_prob

-- above applies to specification (logit , augment)
CO_reduction_wk16_25_completers = arm2 b_gender age_years i.HT2
ftnd_baseline baselinecompositemcigs b_150mins_modvig_week rec_method
mental_health_prob

-- above applies to specification (logit , augment)
w16_reduction_50_completers = arm2 b_gender age_years i.HT2 ftnd_baseline
baselinecompositemcigs b_150mins_modvig_week rec_method mental_health_prob
```

Conditional models:

```
b_co_ppm: pmm b_co_ppm i.b_confquithigh_1 i.wk4_co_quit_completers
i.CO_reduction_wk16_25_completers
i.w16_reduction_50_completers arm2 b_gender age_years
i.HT2 ftnd_baseline baselinecompositemcigs
b_150mins_modvig_week rec_method mental_health_prob
```

```

b_confquithi~1: logit b_confquithigh_1 b_co_ppm i.wk4_co_quit_completers
                  i.CO_reduction_wk16_25_completers
                  i.w16_reduction_50_completers arm2 b_gender age_years
                  i.HT2 ftnd_baseline baselinecompositecigs
                  b_150mins_modvig_week rec_method mental_health_prob ,
                  augment
wk4_co_quit~s: logit wk4_co_quit_completers b_co_ppm i.b_confquithigh_1
                  i.CO_reduction_wk16_25_completers
                  i.w16_reduction_50_completers arm2 b_gender age_years
                  i.HT2 ftnd_baseline baselinecompositecigs
                  b_150mins_modvig_week rec_method mental_health_prob ,
                  augment
CO_reduction~s: logit CO_reduction_wk16_25_completers b_co_ppm
                  i.b_confquithigh_1 i.wk4_co_quit_completers
                  i.w16_reduction_50_completers arm2 b_gender age_years
                  i.HT2 ftnd_baseline baselinecompositecigs
                  b_150mins_modvig_week rec_method mental_health_prob ,
                  augment
w16_reductio~s: logit w16_reduction_50_completers b_co_ppm
                  i.b_confquithigh_1 i.wk4_co_quit_completers
                  i.CO_reduction_wk16_25_completers arm2 b_gender age_years
                  i.HT2 ftnd_baseline baselinecompositecigs
                  b_150mins_modvig_week rec_method mental_health_prob ,
                  augment

```

Performing chained iterations:

```

imputing m=1: burn-in 10 ..... done
imputing m=2: burn-in 10 ..... done
imputing m=3: burn-in 10 ..... done
imputing m=4: burn-in 10 ..... done
imputing m=5: burn-in 10 ..... done
imputing m=6: burn-in 10 ..... done
imputing m=7: burn-in 10 ..... done
imputing m=8: burn-in 10 ..... done
imputing m=9: burn-in 10 ..... done
imputing m=10: burn-in 10 ..... done
imputing m=11: burn-in 10 ..... done
imputing m=12: burn-in 10 ..... done
imputing m=13: burn-in 10 ..... done
imputing m=14: burn-in 10 ..... done
imputing m=15: burn-in 10 ..... done
imputing m=16: burn-in 10 ..... done
imputing m=17: burn-in 10 ..... done
imputing m=18: burn-in 10 ..... done
imputing m=19: burn-in 10 ..... done
imputing m=20: burn-in 10 ..... done
imputing m=21: burn-in 10 ..... done
imputing m=22: burn-in 10 ..... done
imputing m=23: burn-in 10 ..... done
imputing m=24: burn-in 10 ..... done
imputing m=25: burn-in 10 ..... done
imputing m=26: burn-in 10 ..... done
imputing m=27: burn-in 10 ..... done
imputing m=28: burn-in 10 ..... done
imputing m=29: burn-in 10 ..... done
imputing m=30: burn-in 10 ..... done
imputing m=31: burn-in 10 ..... done
imputing m=32: burn-in 10 ..... done
imputing m=33: burn-in 10 ..... done
imputing m=34: burn-in 10 ..... done
imputing m=35: burn-in 10 ..... done
imputing m=36: burn-in 10 ..... done
imputing m=37: burn-in 10 ..... done
imputing m=38: burn-in 10 ..... done
imputing m=39: burn-in 10 ..... done
imputing m=40: burn-in 10 ..... done

```

Multivariate imputation	Imputations =	40
Chained equations	added =	40
Imputed: m=1 through m=40	updated =	0

```
wk4_co_quit~s: augmented logistic regression
CO_reduction~s: augmented logistic regression
  b_co_ppm: predictive mean matching
w16_reduction~s: augmented logistic regression
  b_confquithi~1: logistic regression
```

	Observations per m			
Variable	Complete	Incomplete	Imputed	Total
wk4_co_quit~s	61	38	38	99
CO_reduction~s	61	38	38	99
b_co_ppm	98	1	1	99
wl6_reductio~s	61	38	38	99
b_confquithi~1	97	2	2	99

(complete + incomplete = total; imputed is the minimum across m of the number of filled-in observations.)

```
.
.
. mi estimate, or: logistic CO_reduction_wk16_25_completers i.arm2 i.HT2 age_yea
> rs ftnd baseline b gender
```

Multiple-imputation estimates	Imputations	=	40
Logistic regression	Number of obs	=	99
	Average RVI	=	0.3522
	Largest FMI	=	0.3150
DF adjustment: Large sample	DF: min	=	401.73
	avg	=	645.08
	max	=	801.99
Model F test: Equal FMI	F(6, 3297.1)	=	2.17
Within VCE type: OIM	Prob > F	=	0.0434

CO_reductions	Odds Ratio	Std. Err.	t	P> t	[95% Conf. Interval]	
arm2						
I	4.11417	2.220531	2.62	0.009	1.426096	11.86905
HT2						
MF	.6718333	.491791	-0.54	0.587	.1593264	2.832927
MK	.8461175	.5344147	-0.26	0.791	.2449019	2.923271
age_years	.9887891	.0251047	-0.44	0.657	.9406667	1.039373
ftnd_baseline	.8190198	.1113019	-1.47	0.142	.627196	1.069512
b_gender	.2097143	.1180185	-2.78	0.006	.0694707	.6330743
_cons	29.14493	56.30653	1.75	0.081	.6564979	1293.876

```
. mi estimate, or: logistic w16_reduction_50_completers i.arm2 i.HT2 age_years f
> tnd baseline b gender
```

Multiple-imputation estimates	Imputations	=	40
Logistic regression	Number of obs	=	99
	Average RVI	=	0.5464
	Largest FMI	=	0.4937
DF adjustment: Large sample	DF: min	=	164.08
	avg	=	425.23
	max	=	936.72
Model F test: Equal FMI	F(6, 1879.7)	=	1.34
Within VCE type: OIM	Prob > F	=	0.2361

wl6 reductions	Odds Ratio	Std. Err.	t	P> t	[95% Conf. Interval]
----------------	------------	-----------	---	------	----------------------

-----+-----						
arm2						
I		3.477272	2.18558	1.98	0.049	1.005206 12.0288
HT2						
MF		.5233028	.3454176	-0.98	0.327	.1432754 1.911324
MK		.771393	.4906379	-0.41	0.683	.2210381 2.692057
age_years		1.015212	.0267412	0.57	0.567	.9639171 1.069237
ftnd_baseline		.8888511	.1200149	-0.87	0.383	.6816668 1.159007
b_gender		.4787873	.2742955	-1.29	0.199	.1551316 1.477696
_cons		1.659319	3.265331	0.26	0.797	.0346199 79.53048
-----+-----						

```
. mi estimate, or: logistic wk4_co_quit_completers i.arm2 i.HT2 age_years ftnd_b
> aseline b_gender
```

Multiple-imputation estimates		Imputations	=	40
Logistic regression		Number of obs	=	99
		Average RVI	=	0.6545
		Largest FMI	=	0.4658
DF adjustment: Large sample		DF: min	=	184.30
		avg	=	266.23
		max	=	343.53
Model F test: Equal FMI		F(6, 1454.2)	=	0.74
Within VCE type: OIM		Prob > F	=	0.6175

-----+-----						
wk4_co_quit~s		Odds Ratio	Std. Err.	t	P> t	[95% Conf. Interval]
-----+-----						
arm2						
I		3.11882	2.611602	1.36	0.176	.5985333 16.25146
HT2						
MF		.9103782	.8150607	-0.10	0.917	.1564759 5.296587
MK		.6205256	.5801165	-0.51	0.610	.0985086 3.908814
age_years		1.043336	.0436369	1.01	0.312	.9606997 1.133079
ftnd_baseline		.8482571	.1612168	-0.87	0.387	.5835515 1.233036
b_gender		.8092411	.6259857	-0.27	0.785	.1764895 3.710538
_cons		.0493203	.1443697	-1.03	0.305	.0001551 15.67967
-----+-----						

end of do-file

```
r(2000);
```

```
. use "C:\Users\Tommy\OneDrive\Work\EARS\Output\papers\Main Outcome Paper\STATA
> Files\EARS data ALL 24-09-13.dta", clear

. do "C:\Users\Tommy\AppData\Local\Temp\STD00000000.tmp"

. capture

. mi set flong

. mi query
data mi set flong, M = 0
last mi update 23jun2015 21:24:16, 0 seconds ago

. mi register imputed CO_reduction_wk16_25_completers quit_attempt_made_complete
> rs ///
> w16_reduction_50_completers ///
> b_confquithigh_1 b_co_ppm
(40 m=0 obs. now marked as incomplete)

.
```

```

. mi register regular arm2 baselinecompositemcigs ///
> smoke_years ftnd_baseline b_gender age_years b_150mins_modvig_week ///
> rec_method HT2 mental_health_prob

.

. set seed 29390

.

. mi impute chained (logit, augment) quit_attempt_made_completers (logit, augme
> nt) ///
> CO_reduction_wk16_25_completers (pmm) b_co_ppm (logit, augment) ///
> w16_reduction_50_completers (logit, augment) b_confquithigh_1 ///
> = arm2 b_gender ///
> age_years i.HT2 ftnd_baseline baselinecompositemcigs b_150mins_modvig_week ///
> rec_method mental_health_prob , ///
> add (40) force report chaindots burnin(10) savetrace(extrace, replace)

```

Checking equations:

```

-- above applies to specification (pmm ) b_co_ppm = arm2 b_gender age_years
i.HT2 ftnd_baseline baselinecompositemcigs b_150mins_modvig_week rec_method
mental_health_prob

-- above applies to specification (logit , augment) b_confquithigh_1 = arm2
b_gender age_years i.HT2 ftnd_baseline baselinecompositemcigs
b_150mins_modvig_week rec_method mental_health_prob

-- above applies to specification (logit , augment)
quit_attempt_made_completers = arm2 b_gender age_years i.HT2 ftnd_baseline
baselinecompositemcigs b_150mins_modvig_week rec_method mental_health_prob

-- above applies to specification (logit , augment)
CO_reduction_wk16_25_completers = arm2 b_gender age_years i.HT2
ftnd_baseline baselinecompositemcigs b_150mins_modvig_week rec_method
mental_health_prob

-- above applies to specification (logit , augment)
w16_reduction_50_completers = arm2 b_gender age_years i.HT2 ftnd_baseline
baselinecompositemcigs b_150mins_modvig_week rec_method mental_health_prob

```

Conditional models:

```

b_co_ppm: pmm b_co_ppm i.b_confquithigh_1
i.quit_attempt_made_completers
i.CO_reduction_wk16_25_completers
i.w16_reduction_50_completers arm2 b_gender age_years
i.HT2 ftnd_baseline baselinecompositemcigs
b_150mins_modvig_week rec_method mental_health_prob
b_confquithigh_1: logit b_confquithigh_1 b_co_ppm
i.quit_attempt_made_completers
i.CO_reduction_wk16_25_completers
i.w16_reduction_50_completers arm2 b_gender age_years
i.HT2 ftnd_baseline baselinecompositemcigs
b_150mins_modvig_week rec_method mental_health_prob ,
augment
quit_attempt~s: logit quit_attempt_made_completers b_co_ppm
i.b_confquithigh_1 i.CO_reduction_wk16_25_completers
i.w16_reduction_50_completers arm2 b_gender age_years
i.HT2 ftnd_baseline baselinecompositemcigs
b_150mins_modvig_week rec_method mental_health_prob ,
augment
CO_reduction~s: logit CO_reduction_wk16_25_completers b_co_ppm
i.b_confquithigh_1 i.quit_attempt_made_completers
i.w16_reduction_50_completers arm2 b_gender age_years
i.HT2 ftnd_baseline baselinecompositemcigs
b_150mins_modvig_week rec_method mental_health_prob ,
augment
w16_reduction~s: logit w16_reduction_50_completers b_co_ppm
i.b_confquithigh_1 i.quit_attempt_made_completers
i.CO_reduction_wk16_25_completers arm2 b_gender age_years

```

```
i.HT2 ftnd_baseline baselinecompositēcigs
b_150mins_modvig_week rec_method mental_health_prob ,
augment
```

Performing chained iterations:

```
imputing m=1: burn-in 10 ..... done
imputing m=2: burn-in 10 ..... done
imputing m=3: burn-in 10 ..... done
imputing m=4: burn-in 10 ..... done
imputing m=5: burn-in 10 ..... done
imputing m=6: burn-in 10 ..... done
imputing m=7: burn-in 10 ..... done
imputing m=8: burn-in 10 ..... done
imputing m=9: burn-in 10 ..... done
imputing m=10: burn-in 10 ..... done
imputing m=11: burn-in 10 ..... done
imputing m=12: burn-in 10 ..... done
imputing m=13: burn-in 10 ..... done
imputing m=14: burn-in 10 ..... done
imputing m=15: burn-in 10 ..... done
imputing m=16: burn-in 10 ..... done
imputing m=17: burn-in 10 ..... done
imputing m=18: burn-in 10 ..... done
imputing m=19: burn-in 10 ..... done
imputing m=20: burn-in 10 ..... done
imputing m=21: burn-in 10 ..... done
imputing m=22: burn-in 10 ..... done
imputing m=23: burn-in 10 ..... done
imputing m=24: burn-in 10 ..... done
imputing m=25: burn-in 10 ..... done
imputing m=26: burn-in 10 ..... done
imputing m=27: burn-in 10 ..... done
imputing m=28: burn-in 10 ..... done
imputing m=29: burn-in 10 ..... done
imputing m=30: burn-in 10 ..... done
imputing m=31: burn-in 10 ..... done
imputing m=32: burn-in 10 ..... done
imputing m=33: burn-in 10 ..... done
imputing m=34: burn-in 10 ..... done
imputing m=35: burn-in 10 ..... done
imputing m=36: burn-in 10 ..... done
imputing m=37: burn-in 10 ..... done
imputing m=38: burn-in 10 ..... done
imputing m=39: burn-in 10 ..... done
imputing m=40: burn-in 10 ..... done
```

```
Multivariate imputation          Imputations =      40
Chained equations                added =      40
Imputed: m=1 through m=40       updated =       0

Initialization: monotone         Iterations =     400
                                burn-in =      10
```

```
quit_attempt~s: logistic regression
CO_reduction~s: logistic regression
    b_co_ppm: predictive mean matching
w16_reductio~s: logistic regression
b_confquithi~1: logistic regression
```

Variable	Observations per m			Total
	Complete	Incomplete	Imputed	
quit_attempt~s	62	37	37	99
CO_reduction~s	61	38	38	99
b_co_ppm	98	1	1	99
w16_reductio~s	61	38	38	99
b_confquithi~1	97	2	2	99

```
(complete + incomplete = total; imputed is the minimum across m
of the number of filled-in observations.)
```

```
.
.
. mi estimate, or: logistic quit_attempt_made_completers i.arm2 i.HT2 age_years
> ftnd_baseline b_gender
```

Multiple-imputation estimates	Imputations	=	40
Logistic regression	Number of obs	=	99
	Average RVI	=	0.4345
	Largest FMI	=	0.4801
DF adjustment: Large sample	DF: min	=	173.47
	avg	=	450.86
	max	=	704.03
Model F test: Equal FMI	F(6, 2499.1)	=	1.63
Within VCE type: OIM	Prob > F	=	0.1348

quit_attemp~s	Odds Ratio	Std. Err.	t	P> t	[95% Conf. Interval]
arm2					
I	5.509224	4.345581	2.16	0.031	1.168124 25.98316
HT2					
MF	.5732289	.5128649	-0.62	0.534	.098802 3.325756
MK	.7540211	.6109458	-0.35	0.728	.1535718 3.702162
age_years	1.069635	.0459823	1.57	0.119	.982622 1.164354
ftnd_baseline	.8819846	.1494336	-0.74	0.459	.6323137 1.230239
b_gender	.4301187	.2946473	-1.23	0.219	.1120675 1.65081
_cons	.0283794	.0829416	-1.22	0.224	.00009 8.947116

```
.
. **model for continuous smoking outcomes
.
. capture

. mi set flong

. mi query
data mi set flong, M = 40
last mi update 23jun2015 21:28:20, 5 seconds ago

. mi register imputed co_ppm_wk16_completers wk16_composite_cigs_completers ftn
> d_wk16_completers wk16_reduction_completers ///
> b_confquithigh_1 b_co_ppm
variables b_confquithigh_1 b_co_ppm already registered as imputed
r(110);

end of do-file

r(110);

. use "C:\Users\Tommy\OneDrive\Work\EARS\Output\papers\Main Outcome Paper\STATA
> Files\EARS data ALL 24-09-13.dta", clear

. do "C:\Users\Tommy\AppData\Local\Temp\STD00000000.tmp"

. capture

. mi set flong

. mi query
data mi set flong, M = 0
last mi update 23jun2015 21:29:54, 0 seconds ago

. mi register imputed co_ppm_wk16_completers wk16_composite_cigs_completers ftn
> d_wk16_completers wk16_reduction_completers ///
```



```

> b_confquithigh_1 b_co_ppm
(43 m=0 obs. now marked as incomplete)

.
. mi register regular arm2 baselinecompositecigs ///
> smoke_years ftnd_baseline b_gender age_years b_150mins_modvig_week ///
> rec_method HT2 mental_health_prob

.
. set seed 29390

.
. mi impute chained (pmm) co_ppm_wk16_completers (pmm) ///
> wk16_composite_cigs_completers (pmm) b_co_ppm (pmm) ///
> ftnd_wk16_completers (pmm) wk16_reduction_completers(logit, augment) b_confqu
> ithigh_1 ///
> = arm2 b_gender ///
> age_years i.HT2 ftnd_baseline baselinecompositecigs b_150mins_modvig_week ///
> rec_method mental_health_prob , ///
> add (40) force report chaindots burnin(10) savetrace(extrace, replace)

```

Checking equations:

```

-- above applies to specification (pmm ) b_co_ppm = arm2 b_gender age_years
i.HT2 ftnd_baseline baselinecompositecigs b_150mins_modvig_week rec_method
mental_health_prob

-- above applies to specification (logit , augment) b_confquithigh_1 = arm2
b_gender age_years i.HT2 ftnd_baseline baselinecompositecigs
b_150mins_modvig_week rec_method mental_health_prob

-- above applies to specification (pmm ) co_ppm_wk16_completers = arm2
b_gender age_years i.HT2 ftnd_baseline baselinecompositecigs
b_150mins_modvig_week rec_method mental_health_prob

-- above applies to specification (pmm ) wk16_composite_cigs_completers =
arm2 b_gender age_years i.HT2 ftnd_baseline baselinecompositecigs
b_150mins_modvig_week rec_method mental_health_prob

-- above applies to specification (pmm ) wk16_reduction_completers = arm2
b_gender age_years i.HT2 ftnd_baseline baselinecompositecigs
b_150mins_modvig_week rec_method mental_health_prob

-- above applies to specification (pmm ) ftnd_wk16_completers = arm2 b_gender
age_years i.HT2 ftnd_baseline baselinecompositecigs b_150mins_modvig_week
rec_method mental_health_prob

```

Conditional models:

```

b_co_ppm: pmm b_co_ppm i.b_confquithigh_1 co_ppm_wk16_completers
wk16_composite_cigs_completers wk16_reduction_completers
ftnd_wk16_completers arm2 b_gender age_years i.HT2
ftnd_baseline baselinecompositecigs b_150mins_modvig_week
rec_method mental_health_prob

b_confquithigh_1: logit b_confquithigh_1 b_co_ppm co_ppm_wk16_completers
wk16_composite_cigs_completers wk16_reduction_completers
ftnd_wk16_completers arm2 b_gender age_years i.HT2
ftnd_baseline baselinecompositecigs b_150mins_modvig_week
rec_method mental_health_prob , augment

co_ppm_wk16_~s: pmm co_ppm_wk16_completers b_co_ppm i.b_confquithigh_1
wk16_composite_cigs_completers wk16_reduction_completers
ftnd_wk16_completers arm2 b_gender age_years i.HT2
ftnd_baseline baselinecompositecigs b_150mins_modvig_week
rec_method mental_health_prob

wk16_composi~s: pmm wk16_composite_cigs_completers b_co_ppm
i.b_confquithigh_1 co_ppm_wk16_completers
wk16_reduction_completers ftnd_wk16_completers arm2
b_gender age_years i.HT2 ftnd_baseline
baselinecompositecigs b_150mins_modvig_week rec_method
mental_health_prob

```

```

wk16_reducti~s: pmm wk16_reduction_completers b_co_ppm i.b_confquithigh_1
                  co_ppm_wk16_completers wk16_composite_cigs_completers
                  ftnd_wk16_completers arm2 b_gender age_years i.HT2
                  ftnd_baseline baselinecompositecigs b_150mins_modvig_week
                  rec_method mental_health_prob
ftnd_wk16_co~s: pmm ftnd_wk16_completers b_co_ppm i.b_confquithigh_1
                  co_ppm_wk16_completers wk16_composite_cigs_completers
                  wk16_reduction_completers arm2 b_gender age_years i.HT2
                  ftnd_baseline baselinecompositecigs b_150mins_modvig_week
                  rec_method mental_health_prob

```

Performing chained iterations:

```

imputing m=1: burn-in 10 ..... done
imputing m=2: burn-in 10 ..... done
imputing m=3: burn-in 10 ..... done
imputing m=4: burn-in 10 ..... done
imputing m=5: burn-in 10 ..... done
imputing m=6: burn-in 10 ..... done
imputing m=7: burn-in 10 ..... done
imputing m=8: burn-in 10 ..... done
imputing m=9: burn-in 10 ..... done
imputing m=10: burn-in 10 ..... done
imputing m=11: burn-in 10 ..... done
imputing m=12: burn-in 10 ..... done
imputing m=13: burn-in 10 ..... done
imputing m=14: burn-in 10 ..... done
imputing m=15: burn-in 10 ..... done
imputing m=16: burn-in 10 ..... done
imputing m=17: burn-in 10 ..... done
imputing m=18: burn-in 10 ..... done
imputing m=19: burn-in 10 ..... done
imputing m=20: burn-in 10 ..... done
imputing m=21: burn-in 10 ..... done
imputing m=22: burn-in 10 ..... done
imputing m=23: burn-in 10 ..... done
imputing m=24: burn-in 10 ..... done
imputing m=25: burn-in 10 ..... done
imputing m=26: burn-in 10 ..... done
imputing m=27: burn-in 10 ..... done
imputing m=28: burn-in 10 ..... done
imputing m=29: burn-in 10 ..... done
imputing m=30: burn-in 10 ..... done
imputing m=31: burn-in 10 ..... done
imputing m=32: burn-in 10 ..... done
imputing m=33: burn-in 10 ..... done
imputing m=34: burn-in 10 ..... done
imputing m=35: burn-in 10 ..... done
imputing m=36: burn-in 10 ..... done
imputing m=37: burn-in 10 ..... done
imputing m=38: burn-in 10 ..... done
imputing m=39: burn-in 10 ..... done
imputing m=40: burn-in 10 ..... done

```

Multivariate imputation	Imputations =	40
Chained equations	added =	40
Imputed: m=1 through m=40	updated =	0
Initialization: monotone	Iterations =	400
	burn-in =	10

```

co_ppm_wk16~s: predictive mean matching
wk16_composi~s: predictive mean matching
                  b_co_ppm: predictive mean matching
ftnd_wk16_co~s: predictive mean matching
wk16_reducti~s: predictive mean matching
b_confquithi~1: logistic regression

```

```

-----
|                                     Observations per m
|-----

```

Variable	Complete	Incomplete	Imputed	Total
co_ppm_wk16~s	61	38	38	99
wk16_composi~s	61	38	38	99
b_co_ppm	98	1	1	99
ftnd_wk16_co~s	58	41	41	99
wk16_reducti~s	61	38	38	99
b_confquithi~1	97	2	2	99

(complete + incomplete = total; imputed is the minimum across m of the number of filled-in observations.)

```
.
.
. mi estimate: regress wk16_composite_cigs_completers i.arm2 i.HT2 age_years ftn
> d_baseline b_gender
```

```
Multiple-imputation estimates          Imputations =          40
Linear regression                     Number of obs =          99
                                      Average RVI   =         0.5136
                                      Largest FMI   =         0.4475
                                      Complete DF  =          92
DF adjustment:  Small sample          DF:      min   =         40.97
                                      avg         =         53.09
                                      max         =         60.75
Model F test:      Equal FMI          F(    6,   83.9) =         2.89
Within VCE type:   OLS                Prob > F    =         0.0131
```

wk16_compos~s	Coef.	Std. Err.	t	P> t	[95% Conf. Interval]	
2.arm2	-4.787756	1.920368	-2.49	0.017	-8.6661	-.9094115
HT2						
2	.5118222	2.261366	0.23	0.822	-4.019131	5.042776
3	-.0548172	2.079984	-0.03	0.979	-4.222596	4.112962
age_years	.0492907	.0866315	0.57	0.572	-.1249738	.2235553
ftnd_baseline	1.187596	.435097	2.73	0.009	.3154895	2.059703
b_gender	2.482693	1.740952	1.43	0.159	-.9988501	5.964237
_cons	.7528923	6.259637	0.12	0.905	-11.78036	13.28614

```
. mi estimate: regress co_ppm_wk16_completers i.arm2 i.HT2 age_years ftnd_baseli
> ne b_gender
```

```
Multiple-imputation estimates          Imputations =          40
Linear regression                     Number of obs =          99
                                      Average RVI   =         0.5656
                                      Largest FMI   =         0.4346
                                      Complete DF  =          92
DF adjustment:  Small sample          DF:      min   =         42.17
                                      avg         =         49.43
                                      max         =         56.49
Model F test:      Equal FMI          F(    6,   82.9) =         2.36
Within VCE type:   OLS                Prob > F    =         0.0371
```

co_ppm_wk16~s	Coef.	Std. Err.	t	P> t	[95% Conf. Interval]	
2.arm2	-3.161957	1.8724	-1.69	0.098	-6.92357	.5996552
HT2						
2	-2.668554	2.486591	-1.07	0.289	-7.668278	2.331171
3	-1.652345	2.159146	-0.77	0.447	-5.976812	2.672123
age_years	-.0237663	.0855181	-0.28	0.782	-.1951086	.1475761
ftnd_baseline	.7175693	.4953195	1.45	0.155	-.2813991	1.716538
b_gender	4.492548	2.068442	2.17	0.036	.3187613	8.666335
_cons	7.501701	6.795178	1.10	0.275	-6.138187	21.14159

```
-----
. mi estimate: regress wk16_reduction_completers i.arm2 i.HT2 age_years ftnd_bas
> eline b_gender
```

```
Multiple-imputation estimates      Imputations      =      40
Linear regression                 Number of obs    =      99
                                   Average RVI       =     0.5805
                                   Largest FMI       =     0.4398
                                   Complete DF      =      92
DF adjustment:   Small sample     DF:      min    =     41.68
                                   avg              =     48.13
                                   max              =     54.53
Model F test:      Equal FMI      F(   6,   82.7) =     1.98
Within VCE type:   OLS           Prob > F      =     0.0783
```

wk16_reduct~s	Coef.	Std. Err.	t	P> t	[95% Conf. Interval]	
2.arm2	-33.48698	11.43411	-2.93	0.005	-56.56717	-10.40679
HT2						
2	1.450778	14.14092	0.10	0.919	-26.96522	29.86678
3	3.845525	12.52926	0.31	0.760	-21.26855	28.9596
age_years	-.4047365	.5430139	-0.75	0.460	-1.500798	.6913249
ftnd_baseline	.4540116	2.661244	0.17	0.865	-4.887562	5.795586
b_gender	9.048477	11.25047	0.80	0.425	-13.56307	31.66002
_cons	-22.93496	39.40039	-0.58	0.563	-102.0853	56.21534

```
. mi estimate: regress ftnd_wk16_completers i.arm2 i.HT2 age_years ftnd_baseline
> b_gender
```

```
Multiple-imputation estimates      Imputations      =      40
Linear regression                 Number of obs    =      99
                                   Average RVI       =     0.7253
                                   Largest FMI       =     0.5273
                                   Complete DF      =      92
DF adjustment:   Small sample     DF:      min    =     34.02
                                   avg              =     41.76
                                   max              =     52.60
Model F test:      Equal FMI      F(   6,   80.3) =     7.14
Within VCE type:   OLS           Prob > F      =     0.0000
```

ftnd_wk16_c~s	Coef.	Std. Err.	t	P> t	[95% Conf. Interval]	
2.arm2	-1.566894	.5653331	-2.77	0.009	-2.715759	-.4180293
HT2						
2	.0640968	.7058175	0.09	0.928	-1.364103	1.492297
3	-.0666743	.5789312	-0.12	0.909	-1.228069	1.094721
age_years	-.0320475	.0245305	-1.31	0.198	-.081522	.0174269
ftnd_baseline	.6222427	.1220492	5.10	0.000	.3771858	.8672997
b_gender	.9257517	.5883689	1.57	0.125	-.2698227	2.121326
_cons	.6329279	1.956565	0.32	0.748	-3.32305	4.588906

```
.
end of do-file
```

Exercise Assisted Reduction then Stop smoking

EARS Health Trainer Manual

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EARS Health Trainer Manual
PART 1: Background and Knowledge
PART 2: Intervention

October 2012

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(with input from Health Trainers: Mel Fairbairn, Julie Lloyd & Maggie Kelly)
University of Exeter

This manual is designed to build on the DoH Health Trainer manual. Knowledge and competencies acquired through the City & Guilds HT training are assumed.

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234		
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 - 7.4.4 Physical activity
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 - 7.5.6 How much does smoking cost you?
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- 7.5.12 Champix guide
- 7.5.13 Zyban guide

2 The EARS Project

EARS: Exercise Assisted Reduction then Stop smoking

2.1 Background and objectives

2.1.1 NHS stop smoking services

- NHS Stop Smoking Services aims to help smokers to remain abstinent after an abrupt quit attempt and behavioural and pharmacological support increases success rates by four fold (compared with self-initiated attempts) but as few as 22% are still abstinent one year later.
- No more than 5% of smokers receive NHS Stop Smoking Services when attempting to make an abrupt quit.
- Little or no NHS support is currently available for the 60% of smokers who typically report that they would like to reduce the number of cigarettes smoked.
- Almost half of adults in Devonport and Stonehouse, in Plymouth, smoke. This is double the prevalence across Plymouth as a whole.
- New options are needed to help smokers who wish to reduce smoking but not quit...
- Those who do reduce smoking are more likely to decide to quit, and remain abstinent.

2.1.2 Physical activity and smoking cessation

- Physical activity can help to increase cessation rates among abrupt quitters (Ussher et al, 2008), though less is known about effects for 'hard-to-reach' smokers.
- Physical activity (structured exercise and short bouts of movement) reduces cravings and withdrawal symptoms, limits increases in cravings associated with smoking cues, and delays the time between smoking cigarettes.
- Extensive pilot work has taken place to see how best to promote physical activity as an aid to making an abrupt quit attempt, in Plymouth and other NHS Stop Smoking Services (SSS), with input from advisors and smokers.
- This involved a self-help guide, pedometers, and behaviour change strategies, such as setting goals and reviewing progress.
- Physical activity has not previously been rigorously assessed as a strategy to help smokers to reduce, then possibly quit and remain abstinent.

2.1.3 Introduction to EARS

- The Department of Health wish to determine if smokers who wish to cut down but not quit, can be supported in this adjustment with a Health Trainer, providing behavioural support.
- The Health Trainer role will be to support both a reduction in smoking, using a variety of options, and to help smokers to increase their physical activity, again through a variety of personal choices.
- Smokers who reach the point where they wish to quit will be offered the full range of NHS Stop Smoking Service professional support, with maintained support from the Health Trainer.
- In Phase 1 of the study (from September 2010-March, 2011), we will identify the best way to engage with smokers who wish to reduce smoking but not quit, within Devonport and Stonehouse, through interviews and discussions with a variety of relevant stakeholder groups and individuals.
- In Phase 2 of the study (from April, 2011-April, 2012), we aim to recruit 120 such smokers in these areas of Plymouth, equally from GP practices and non-primary care sites (e.g. community centres).
- All will be asked to provide information about lifestyle, health and related thoughts initially and at several points in the study, over 4 months. Through a procedure called randomization volunteers will be allocated to one of two groups.
 - Sixty smokers will be encouraged to cut down as they normally would, and given information about NHS Stop Smoking Services, to access if they wish to quit.
 - Sixty smokers will be offered the weekly support of a Health Trainer, in person or by phone, to reduce smoking and increase physical activity. There will be a variety of options offered to support both smoking reduction and increasing physical activity.

2.1.4 How do smoking and physical activity link?

- When smokers cut down they find it easier to breath and this helps them to become more active, doing some of the things they haven't enjoyed for a while.
- Increasing physical activity can help in several ways:
 - It can reduce an urge to smoke as the period between cigarettes increases while reducing smoking.
 - It can reduce withdrawal symptoms such as stress and anxiety, low mood, irritability, restlessness, and hunger, in the absence of a cigarette.

- It can serve as a distraction and become a new interest to replace the habitual need for a cigarette in certain situations.
- If a quit attempt is made, it may be easier to become more physically active first, rather than trying to change two behaviours at the same time.
- Doing some physical activity can remind a smoker just how breathless they have become, and this can prompt a desire to quit.
- Fears about quitting, such as inability to cope with life's demands, and weight gain, can be reduced as physical activity helps with both of these.
- Becoming more physically active can lead to a shift in identity away from that of a smoker.

2.1.5 Will smokers be interested in EARS?

- ☑ A survey of 178 smokers in a Plymouth GP practice found 62% were prepared to gradually cut down, of whom 70 (39% overall) were 'interested in taking part in a research study to see if physical activity is useful to reduce the amount you smoke.' We added in the survey: '(The study would include support such as professional support, a self-help booklet, a free pedometer, and free access to an exercise facility).'

But a big part of this study is also to answer this question. How can we recruit people from different backgrounds with different needs, into such a study, and to engage in the intervention?

2.2 Summary of Research Protocol

EARS has been designed as a pilot, pragmatic, randomised controlled trial (RCT), to which participants who wish to reduce their smoking but not quit within the next month will be recruited and randomly assigned to one of two groups:

- 1) **Brief Advice** provided at baseline by the Health Trainer (HT) in the form of written and verbal information on the NHS SSS with information on the benefits of quitting and how to quit. Those expressing a desire to quit will be subsequently referred to the NHS SSS.
- 2) **Health Trainer behavioural support** in the form of written and verbal information on NHS SSS with information on the benefits of quitting and how to quit provided at baseline. Smokers will select one of 4 strategies for smoking reduction while also being encouraged to become more physically active through about 3 face-to-face and 5 telephone communications, over 8 weeks. Client-centred counselling will focus on exploring beliefs about increasing physical activity and its use to reduce smoking,

action planning (or SMART goal setting) and supporting behaviour change. The HT will seek to develop a supportive relationship, and provide guidance on using a free pedometer, an MP3 player (with an isometric exercise recording), self-monitoring and other self-regulating techniques, and signpost smokers to local exercise opportunities with subsidised access as required. Those expressing a desire to make a quit attempt will subsequently be referred to a professional NHS Stop Smoking Service advisor, with concurrent HT support over a further 6 weeks.

Standardised brief advice to be given to all participants after randomisation:

Plymouth Smoking Advice Service

Our EARS study involves those who wish to cut down but not quit in the next month.

However, if you do feel that you wish to quit at any time then specialist help is available from Plymouth Smoking Advice Service for those who wish to quit.

Trained professionals can support you with advice and access to a range of therapies, including Nicotine Replacement Therapy (gum, patches, etc).

This support can greatly increase success rates in quitting, compared with going it alone.

As someone in a research study we would like you to contact us first at 01752 434438 if you do wish to quit, during the 4 month study.

We will then refer you to:

Plymouth Smoking Advice Service,
Devonport & Stonehouse Office,
Room F24, Cumberland Centre,
Dammerel Close,
Devonport.
Tel: 07917072874



2.3 What changes are we looking for?

All individuals who receive the EARS intervention are hoped to achieve the following changes:

Main outcomes:

We want to see more:

- *Quit attempts (during period up to 12 weeks)*
- *CO confirmed abstinence (at 4 weeks post quit)*
- *Smokers achieving a 50% reduction in smoking*

Secondary outcomes:

We want to see more:

- *Moderate and/or vigorous minutes of physical activity (self-reported and from accelerometer recordings)*
- *More favourable beliefs about the value of PA as an aid for smoking reduction.*
- *More positive beliefs about confidence to do PA*
- *More positive beliefs about confidence and importance of quitting.*

We want to see less:

Methodological outcomes:

We want to see:

- *At least 120 smokers recruited and randomised within the study*
- *Maximise contacts with participants.*
- *Evidence of fidelity to delivery of the intervention as per*

2.4 EARS and the role of the Health Trainer

What follows is a brief overview of the role of the EARS Health Trainers. A more detailed description and session by session breakdown is provided from Section 3 onwards.

From the participants' perspective the intervention will last for up to 8 weeks + 6 weeks additional support during a quit attempt.

2.4.1 The Intervention

The initial session will be held at either a community venue, a GP practice, or other clinical setting. It is expected to last around 1 hour.

Working together the HT and participant will discuss feelings and attitudes towards smoking behaviour and physical activity. Being heavily client-centred, the HT and participant will agree on goals for the participant to work towards in terms of smoking reduction and physical activity. The goals should be tailored to the individual participant, with week by week short term goals building in to a longer 8 week goal. General indicators would be a smoking reduction of 50% over 4 weeks with further reduction in the following 4 weeks, and an increase in PA to the maximum of the individual's desire/capability. Over the next 6 weeks the HT will provide weekly phone calls to offer support and guidance for the participant in achieving their goals, and at 8 weeks the HT will meet the participant again for a final face-to-face session to review progress and discuss maintenance plans.

Whilst it is not within the aims of the HT to support a quit attempt, if at any time (up to 8 weeks from initial session) the participant desires to quit the HT will refer them to NHS SSS.

The HT will also make weekly support phone calls for 6 weeks during the quit attempt.

The aims of the intervention package are to:

- Promote sustained increases in physical activity
- Encourage sustained smoking reduction
- Empower individuals to control cravings through PA
- Provide information on local PA opportunities as necessary
- Promote positive experiences and rewards from PA
- Refer to appropriate services and provide support through any quit attempt

3 Core Knowledge and Skills

The concept of the Health Trainer (HT) was originally proposed in the 2004 Department of Health White Paper: *Choosing Health: Making Healthy Choices Easier*. HTs are traditionally people drawn from local communities and are trained to reach those who want to adopt healthier lifestyles but have little contact with services. HTs develop an understanding of the needs of people from deprived communities and apply basic behaviour change techniques. They typically embed themselves in communities in order to increase the reach of their service to the more ‘hard to reach’.

This section assumes the trainee has developed the core HT competencies with respect to:

1. Making relationships with communities.
2. Communicating with individuals about promoting their health and well-being.
3. Enabling individuals to change their behaviour to improve their own health and well-being.
4. Managing and organising own time and activities.

3.1 The role of the EARS Health Trainer

The role of the HT has been adopted in the EARS study because a client-centred intervention is planned for ‘hard to reach’ smokers.

Whilst the traditional health trainer assesses the client’s desire to address a particular behaviour from a choice of usually four behaviours (alcohol consumption, diet, smoking and physical activity) the EARS HTs will only focus on *smoking reduction and cessation and physical activity, and their interaction*. The EARS HTs will draw upon the skills and knowledge equivalent to the City and Guilds Level 3 HT qualification, but will adapt these skills in line with the EARS protocol and this training manual.

In summary, the present manual particularly builds on HT competency number 3 (see above), described in detail in the NHS Health Trainer Handbook, ‘Improving Health: Changing Behaviour.’ Department of Health & British Psychological Association, 2008. This competency (see p. 18 in this Handbook) is about enabling individuals to:

1. Identify how behaviour affects their health.
2. Develop a Personal Health Guide (action plan).
3. Change and maintain a health behaviour.

3.2 Smoking Addiction and Treatment

Smoking is the single biggest preventable cause of death in the world and the World Health Organisation predicts it will account for 8 million deaths per year globally by 2030. Half of those who smoke will die from, or succumb to disease directly resulting from, their smoking habits.

In the UK, the NHS spent £73 million on Stop Smoking Services in 2008/09, not including pharmacotherapy costs. The amount invested in services has risen steadily over the last decade, yet despite this fewer people successfully made a quit attempt in 2008/09 than in 2007/08.

Success rates among those who attempt to quit alone, without behavioural support or pharmacotherapies are extremely low – only around 3-5% will still be non smokers 12 months after quitting.

The UK has also seen greater resources directed towards helping 'hard to reach' groups in an attempt to address health inequality. Yet, despite this, smoking prevalence is reducing at a slower rate among the social grades C2-E than social grades AB-C1 (1.3% and 2.3% between 2007-08, respectively).

New approaches are needed to increase the number of 'hard to reach' smokers making a quit attempt with the best available support and hence successfully quit. With no provision available for the 57-66% of smokers who wish to cut down, and the evidence that those who cut down are more likely to make a quit attempt, the EARS intervention aims to assess whether a smoking reduction programme is a successful way to engage with 'hard to reach' smokers, and subsequently increase the number of people making a quit attempt.

3.2.1 Nicotine

Nicotine is a highly addictive psychoactive stimulant. Cigarette smoking is a highly effective delivery method for nicotine, with a lag time of only 7-15 seconds from inhalation to reaching the brain (compare this to up to 20 minutes for nicotine gum).

Thus use of NRT in different forms does not have the same addictive properties (though may still have consequences for health) and is licensed to support smoking reduction and cessation. It does have side effects (see Appendix 7.5.11) and may not be suitable for everyone.

3.2.2 Mood and negative affect

As time increases between each cigarette, a smoker's withdrawal symptoms and cravings will begin to rise. This leads to an increase in negative mood states such as low mood, irritability, anxiety, tension, hunger and stress. Drug seeking behaviour (needing to smoke a cigarette) in order to alleviate these negative feelings is common. In a sense, a smoker's satisfaction from a cigarette comes from the alleviation of negative mood states – they smoke to feel normal (see Figure 1).

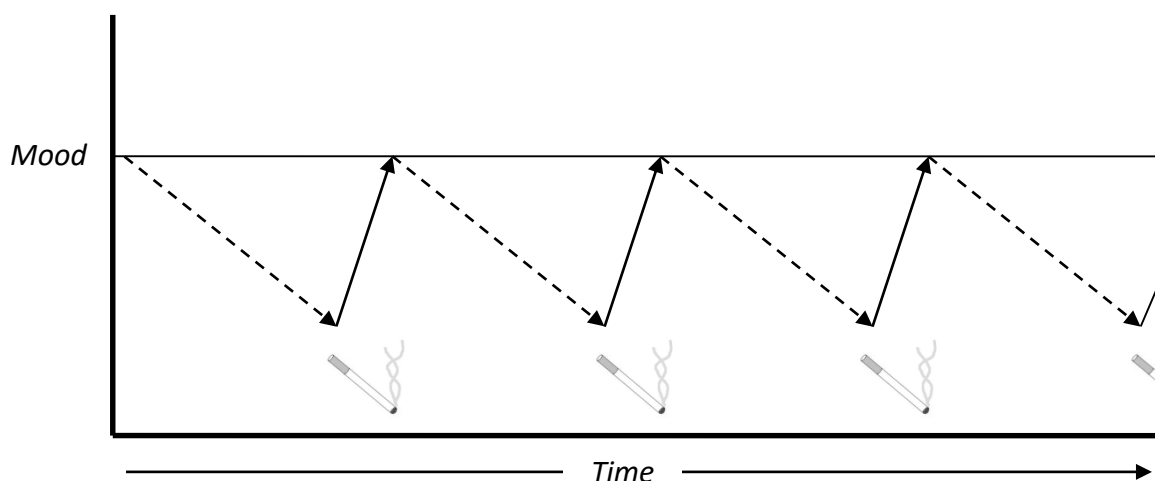


Fig.1 Graphical representation of smoking and mood

It is worth noting that reported reasons for smoking are often paradoxical in nature – people will smoke both for stimulation and for relaxation. Nicotine is a stimulant which can increase perceived alertness and concentration, and yet also relieve stress. Despite reports that smoking relieves stress, it has been shown that smokers generally exhibit higher stress levels than non-smokers. There is no evidence of a causal relationship (whether people with high stress levels tend to be drawn towards smoking or if smoking causes higher stress levels), but it has interesting implications for physical activity as discussed in Section 2.5.

3.2.3 Cue Reactivity

People often smoke as a result of being exposed to a certain situation or cue (such as having a drink in the pub or after a meal). The desire for a cigarette is stimulated by a learned response to a given stimulus. This form of classical conditioning where a conditioned response follows a conditioned stimulus is often developed over a long period of time and can be very hard to break. Psychological stress is often cited as a cue to smoking.

Cues provide opportunities for impulsive behaviour, which is not planned. So self-regulation and inhibiting a learned response (e.g. having a cigarette when offered one) is challenging. Learning ‘what-if’ strategies are often an important weapon to avoid lapses triggered by cues.

3.2.4 Reasons for smoking/Barriers to quitting

The reasons people smoke and the barriers which prevent people from quitting are often complex and numerous. Whilst EARS is primarily concerned with supporting people to cut down and not helping them to decide to quit, it is worth noting possible why people start and the barriers to them stopping as they can relate strongly to the role of physical activity.

Reasons for smoking	Barriers to quitting
<ul style="list-style-type: none"> • Boredom • Smoking is part of a social activity • Smoking is used as a coping strategy for when things get stressful or difficult • Used as a weight management strategy • Enjoyment • Exposure to conditioned stimulus • For stimulation • For relaxation 	<ul style="list-style-type: none"> • Lack of confidence to quit (previously failed quit attempts) • Fear of withdrawal symptoms • Motivation • Desire • Belief that smoking isn’t dangerous • Peer pressure • Social exposure • Loss of smoking as a stress management tool • Lack/cost/availability of support and NRT • Powerful addiction to nicotine

Table 1. Reasons for smoking and barriers to quitting

One important reason for sustaining smoking and for relapsing from a quit attempt is **weight gain**. Nicotine increases metabolism and suppresses appetite, so when someone stops smoking they will gain, on average, 7kg in 12 months. The weight gain is compounded by the potential replacement of the nicotine ‘hit’ with indulgent snacking and emotional eating. For many, even minimal weight gain is unacceptable, so strategies to prevent weight gain after smoking cessation are required. There is no evidence for what effects smoking reduction has on weight gain.

3.3 Abrupt quitting

At this time, the NHS Stop Smoking Service largely advocates abrupt approaches to quitting. With the support of a qualified stop smoking advisor, those wishing to quit will work to set a quit date, following which they will attempt to not smoke another cigarette. They will be offered the option of using a variety of pharmacotherapies (Nicotine Replacement Therapy (NRT), Bupropion, Varenicline etc) to help manage cravings and withdrawal symptoms. Even the most optimistic data suggests that with the best pharmacological and behavioural support, the chance of remaining abstinent 1 year post quit only rises to around 20% from around 3% unaided.

It is estimated the NHS SSS only engages with around 5% of smokers at any one time. The reach of the NHS could be limited by the fact it only engages with those who express a desire to quit abruptly, as well as a perception that smoking is not a clinical problem which required 'treatment'.

3.4 Advanced reduction and cessation

3.4.1 Why quit?

Appendix 7.4.2 shows some of the advantages of quitting, over different time periods. The DoH HT Handbook also includes a Health Benefits card (see p. 17), which can be used to elicit smoker beliefs.

3.4.2 Why is it hard to quit?

There are many reasons, but the main ones are failure to cope with cravings and withdrawal symptoms (particularly during times of stress, or in the presence of smoking cues), difficulty in breaking a habit or conditioned responses in certain environments and situations, lack of confidence in avoiding smoking perhaps developed from previous failed attempts, being surrounded by others who offer limited support to quit, and weight gain. Alcohol consumption has also been linked to difficulties in avoiding smoking.

3.4.3 What support is available that is effective?

Appendices 7.5.11, 7.5.12 and 7.5.13 provide information on the use of NRT, Champix and Zyban which are the main pharmacotherapies with an evidence for effectiveness. These are

most often prescribed by a clinical practitioner or fully trained Stop Smoking Service advisor. NRT is also available over the counter. Behavioural support is available through Stop Smoking Services and other trained professionals, which is also effective, and often delivered in conjunction with pharmacotherapies.

3.4.4 Building on the DoH Health Trainer Handbook

Smoking cessation is one behaviour that HTs are encouraged to support. However, without extensive training, if a client wishes to quit then an HT would normally refer a client to a professional with the skills to provide the support described above. The focus in the HT Handbook is on helping smokers to abruptly quit by setting a quit date and completely abstaining. There is little or no mention of smoking reduction in as a shift towards this approach is fairly recent, and is only recommended in conjunction with NRT. Since 60-70% of smokers want to cut down but not quit smoking reduction interventions are seen as a way of increasing the number of smokers who potentially get to the point, after reduction, of wanting to quit.

EARS aims to increase physical activity in the absence of NRT, but in conjunction with behavioural approaches to smoking reduction. In the following sections, different smoking reduction approaches are described, before we consider how physical activity can be promoted, and particularly in a way that could support smoking reduction, and cessation.

3.5 Behavioural approaches to smoking reduction

Smoking reduction has not been advocated as an appropriate technique for quitting as it has been widely believed that increasing the amount of time between cigarettes will only increase the reward and satisfaction obtained from the cigarette when it is smoked, thus increasing the value and desire of each cigarette.

Research in this area is still in its infancy, but a recent review by Aveyard et al (2010) has reported that there is no difference between abrupt quitting and cutting down to quit on long term cessation, but this is based on interventions involving Nicotine Assisted Reduction then Stop (NARS).

Several potential strategies for cutting down have been developed and proposed over recent years. Crucially they all hinge on breaking the conditioned responses to smoking stimulus. Unlike abrupt quitting, they aim to gradually breakdown learned routines and break habits

which may increase confidence and desire to stop completely. The different strategies are presented in the following sections.

3.5.1 Hierarchical reduction

Certain cigarettes offer higher reward value than others and as such are harder to give up. The first cigarette in the morning (following overnight abstinence) is routinely reported to be the hardest to give up. It has even been suggested that the only question of importance in assessing a person’s level of smoking dependence is ‘how soon after waking do you smoke your first cigarette?’

Hierarchical reduction works by asking people to rank cigarettes in order of the easiest to the hardest to give up. Starting with the easiest, smoker’s plan which ones they will give up on a specified time scale. It may be one a day over a two week period or however the person feels best to progress, eliminating the easiest and eventually beginning on the harder cigarettes to give up, as confidence to go without a cigarette increases.

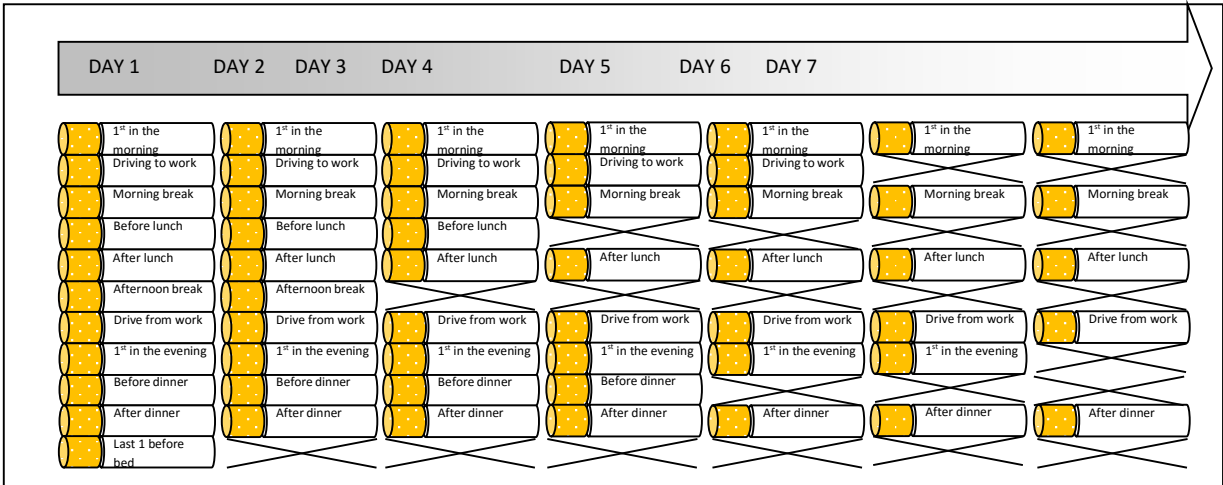


Fig.2 First illustration of hierarchical reduction method

3.5.2 Smoke free periods

The Smoke free periods approach works by breaking an individual’s day up into blocks of specified time periods (eg 30 mins). Depending on their routine (work etc) there may be periods where they do not smoke anyway, and periods where they smoke more. Using chart, smokers then go on to block out certain times of the day where they will not smoke (perhaps increasing by one 30 minute smoke free period per day) until they have reached a certain goal.

Importantly with the smoke free periods approach, there is no specified number of cigarettes which are being cut out or smoked. They can smoke as much as they like, but ONLY in the periods not identified as smoke free. This approach aims to break the behavioural pattern of smoking which will result in a decreased desire for smoking and a natural reduction.

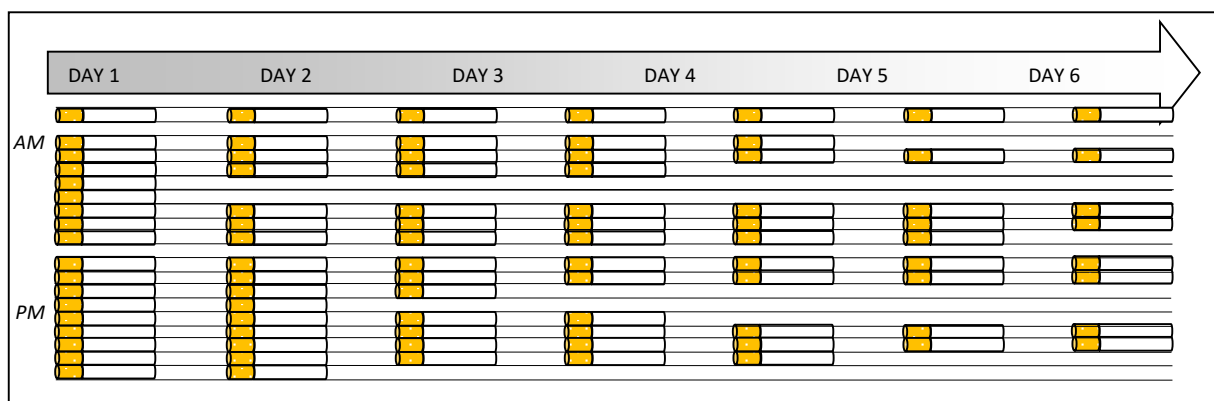


Fig.3 Second illustration of hierarchical reduction method

3.5.3 Scheduled reduction

The aim of the scheduled reduction approach is to systematically reduce at a specified rate, breaking habit and routine gradually. It begins with identifying how many cigarettes a person smokes in a day, and calculating how much time between each cigarette is needed to space them evenly through the day. For example, a 40 a day smoker, who is awake for 16 hours a day, would need to smoke a cigarette every 24 minutes to get through 40 in one day. Targets are then set to gradually increase the time between each cigarette with a specific end goal in sight.

Important to this method is the necessity to smoke at every specified time point, whether it's desired or not, which again helps to break the habit of smoking.

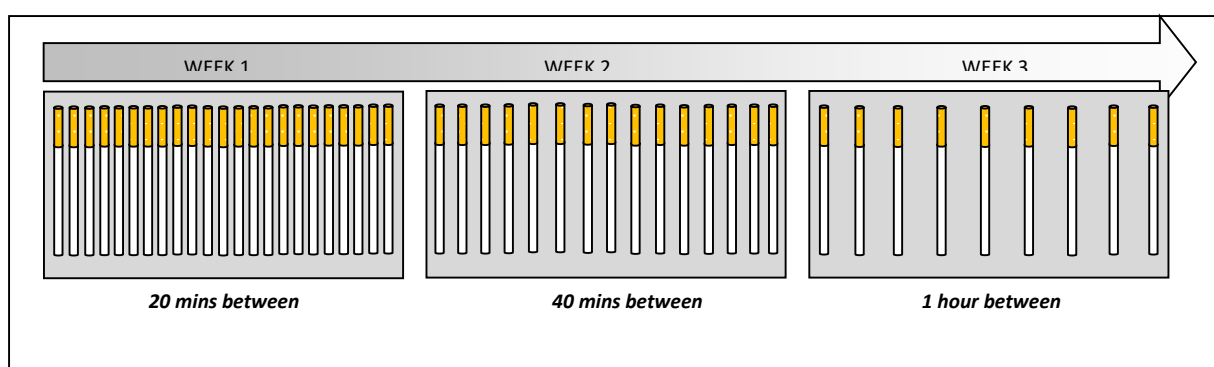


Fig.4 Illustration of scheduled reduction method

3.5.4 Planned reduction

Perhaps one of the simplest ways to plan reduction, this approach works by setting targets for how many cigarettes will be smoked each day. Then each day begins with that number in their pocket, and purchasing additional ones is to be avoided.

The rate at which they reduce is determined by them and ultimately how much they want to reduce by and over what period. This approach fits particularly well with goal setting and action planning processes described in the HT Handbook.

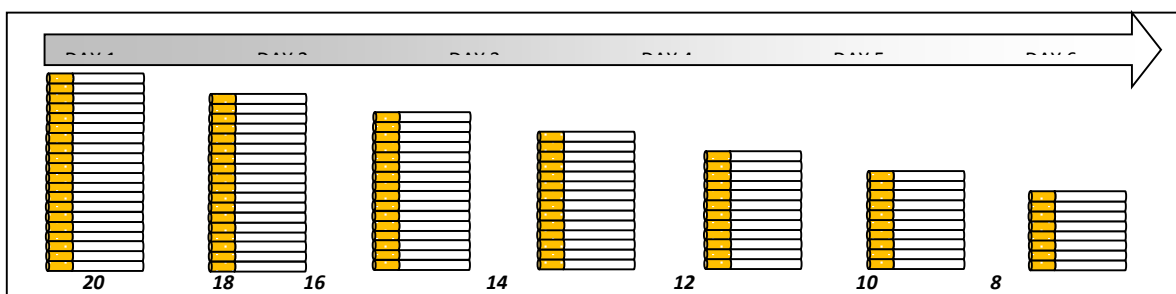


Fig.5 Illustration of planned reduction method

All the above approaches have their pros and cons. The key will be to enable smokers within EARS to choose an approach to experiment with, and to help set a timescales for rate of reduction, as part of the action planning process. Our ideal would be to reduce by 50% over no more than 4 weeks, and then consider further reductions. But there will be considerable variation in participants' responses and success.

3.6 Physical activity and health, optimal dose and promotion

"If some of the benefits accruing from regular physical activity could be procured by any one medicine, then nothing in the world would be held in more esteem than that medicine".

Francis Fuller 1705

Physical activity is widely accepted to benefit health both physically and mentally. Being regularly active decreases the risk of developing an extensive range of medical conditions such as: cardiovascular disease, diabetes, cancer, depression, anxiety, dementia, high blood pressure, osteoporosis, osteoarthritis, lower back pain and lowers the risk of falls among the elderly.

The Department of Health recommends that adults achieve at least 30 minutes of moderate intensity physical activity on at least 5 days of the week, 3 x 20 mins of vigorous physical

activity for cardiovascular health. Activity does not have to be continuous for 30 minutes but can be in shorter 10 minutes bouts throughout the day.

The dose for improving mental health is less clear, although 1 study suggested this same dose would be necessary to reduce depression. Short bouts of moderate physical activity can relieve stress and tension, whilst improving a sense of pleasure and activation. The figure below shows how regular short bouts throughout a day can help to elevate overall mood.

Importantly, by breaking physical activity into short bouts, it may become easier to meet the daily recommended dose in a sustainable way.

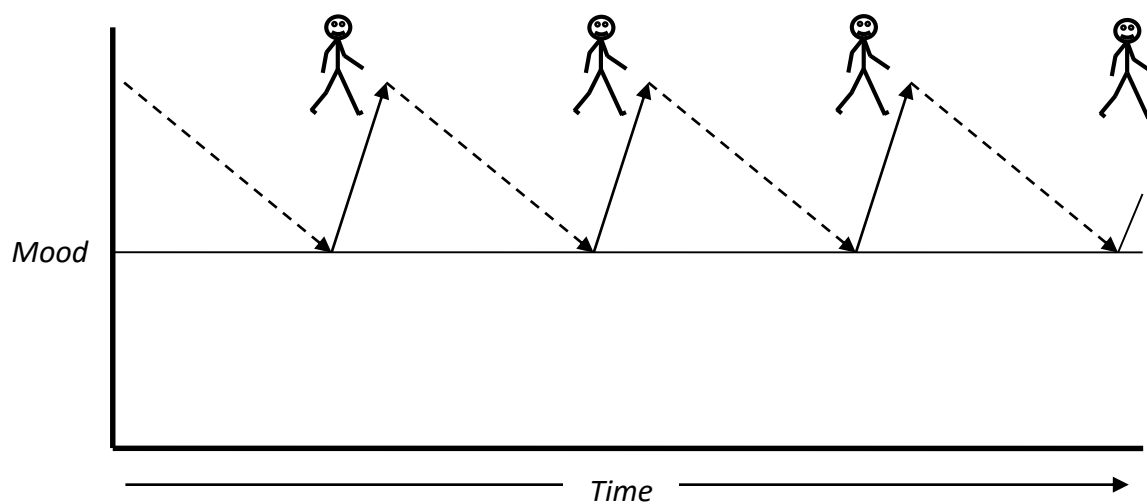


Fig.6 Graphical representation of physical activity and mood

Using a Decision-Balance sheet, as shown in the DoH HT Handbook (p.26), it is easy to identify the pros and cons of becoming more active. But the commonly cited barriers shown below are largely a function of how we introduce or use the terms sport, exercise and physical activity. Short bouts of brisk walking do not have the same barriers as signing up for an exercise class or joining a sports club.

Commonly cited barriers to different types of physical activity.

- *I've never done it*
- *I wasn't good at sports at school*
- *I would feel silly*
- *Other people would make fun of me*
- *It won't help unless it hurts - 'No pain, no gain'*
- *It's sweaty and uncomfortable*
- *I'm too tired*

- *I would rather do something else*
- *It's expensive*
- *I think it will make me feel worse*
- *I don't have anyone to do it with*
- *I don't know where, when or how to start.*

There are a number of factors which can influence how people relate to and perceive different types of physical activity. Typically activity is thought of in four or five different dimensions: Frequency, Intensity, Duration and Type. Timing is less commonly considered but may also be important in the context of using physical activity to specifically help cope with cigarette cravings.

Frequency: How often does the behaviour occur? Is it better to do some physical activity every day or just once in a longer block at weekends? For cardiovascular health, it does seem to be important to regularly exercise. Long periods of sedentary behaviour are increasingly being linked to increased risk of some health problems such as diabetes. The evidence is less clear for other conditions but we do know that even short bouts of activity can increase activation or energy levels, increase positive affect and reduce our natural psychological and physiological responses to stress or threatening situations. Therefore, repeated bouts may lead to an accumulated benefit over a period of time which one longer single session per week may not provide.

Intensity: How intense is the activity? How much effort or physical and mental discomfort does a person experience? The experience of how intense an exercise is can be highly individual, and may depend on several factors such as cardiovascular fitness, fatigue, previous experience, mood, and any existing physical disability.

Intensity	What is it?	PROS	CONS
VIGOROUS E.g. Running, hard cycling, squash, aerobics, circuit training, hard manual work, team sports	An activity that leaves you feeling (extremely) out of breathe and unable to hold a conversation. Your heart rate will rise significantly and will often lead to high levels of perspiration. Breathing will become very rapid and heavy.	Evidence suggests it offers the most physical benefits for those who complete it. Can offer a greater sense of achievement and ‘feel good factor’ for the right person.	Extremely off putting to most, especially people new to physical activity. Can cause delayed muscle pain (not necessarily serious, just uncomfortable) The risk of injury is greatly increased. Often needs specialised equipment and environments (cost) to do it, with high levels of supervision. For smokers it may exacerbate symptoms of breathlessness.
MODERATE E.g. Brisk walking (complete 1 mile in around 15 minutes), cycling, effortful housework, gardening, golf, tennis, dancing, tai chi.	An activity which still allows you to hold a conversation, but you will still feel your heart rate rise, your skin warm and your breathing become slightly faster.	Is easily achievable for nearly everyone. Easily accessible and can be done without high levels of supervision. Still has significant benefits for health (national guidelines promote MODERATE activity)	People may not think of moderate activity as having any benefits (too easy) Slightly increased risk of physical injury, but it is minimal
LOW E.g. slow walking/ strolling, easy housework, light gardening, yoga.	An activity which is very easy to complete, only slightly raises heart rate and does not require faster breathing.	It can be a good starting point for increasing motivation and confidence to complete physical activity for those with little or no experience. Can increase confidence and self belief in moving onto moderate activity. Very small risk involved. Any energy expenditure is better than sitting.	Conveys little or no health benefits.

Table 2. Pros and cons of physical activity of different intensities

Duration: How long does the activity have to take place for? Is it in one long block or broken into smaller chunks?

- Presenting people with the task of walking or cycling continuously for an hour or even 30 minutes can seem daunting and lowers motivation and confidence. Breaking activity up can make it seem more achievable and easier to fit into people's lives.
- The national guidelines suggest 30 minutes of daily moderate activity can be achieved in blocks of 10 minutes. Therefore, someone could walk briskly to work or shops in the morning, take a short 10 minute walk at lunch time and walk home again and they would meet the minimal recommended guidelines for physical activity. This can often be perceived to be far more achievable than one longer walk.

Timing: What time of the day, or maybe week, are people completing physical activity? This is perhaps one of the less considered aspects of physical activity, but remains important none the less.

- It could be that a person aims to complete a walk first thing in the morning, but in reality they are pushed for time in the morning and simply cannot sustain it. Or, perhaps more detrimentally, the idea of going for a walk in the morning becomes a burden and adds pressure to them at a time when they feel they simply cannot fit it in, resulting in feelings of guilt for having not done it.
- It could also be that exercising vigorously or in a way that is unfamiliar in the evening can result in disturbed sleep as a result of a raised body temperature and hormonal responses.
- A person may also gain enjoyment from completing the same activity at different times of day. For example, they may enjoy walking the dog early in the morning compared to late at night because of the different environments (light vs dark) and feelings of safety. They may also want to do it after a busy day to 'unwind'.

Mode: Physical activity takes many different forms and can serve many different purposes. It is important to know what *type* of physical activity a person believes they may enjoy/have enjoyed in the past. Running can be completely off putting for one individual, but potentially rewarding and enjoyable for another.

- Promoting an activity which a person does not enjoy will likely limit adoption and maintenance of that activity.

- It is important to consider that although an individual may not enjoy an activity of a certain intensity (such as jogging), they may however enjoy an alternative activity of a similar intensity but different mode (eg cycling).
- Certain modes of activity can also have time implications. For example, arranging a game of badminton can require travelling time, perhaps a minimum court booking of an hour, and may depend on facility opening times. Compare this with taking a walk, which needs little preparation and planning and can be completed at most times of the day.
- Different modes of activity can also have different cost implications. Cost is often a large barrier to the adoption and continued participation in certain activities. The cost of going for a walk is minimal compared to going for a cycle if the person does not own a bike.

There are some other important psychosocial factors surrounding physical activity which can strongly influence its successful adoption and enhance the positive experience of being physically active:

Environment: It is entirely plausible that the location in which an activity takes place will influence how an individual experiences that activity. Walking on a treadmill in a gym will provide an entirely different experience to walking through a country park, despite being the same *physical* activity. The experience of one exercise or yoga class may be entirely different to another class with a different instructor elsewhere.

It is also important to consider how an environment has the potential to damage an individual's confidence and motivation. For example, attending a heavily strength and weights orientated gym can be a highly off putting experience for a beginner or somebody with low physical self-esteem. A bad experience of a physical activity environment can make it highly unlikely for the behaviour to re occur.

Social Support: Can be considered in two forms – in terms who the activity is done with and support from others for completing the activity.

Going for a walk with a friend can enhance the enjoyment of the activity, and agreeing to attend a new exercise class with a friend will enhance the motivation and confidence for continued attendance. Whilst it can often be reported that completing physical activity alone can offer

enjoyment (a chance to ‘get away from it all’, to ‘clear your head’), completing it with others can go some way to fulfilling the psychological need to feel connected with others.

Support from significant others (friends, family, partners, etc) in relation to completing an activity is also important in adopting and maintaining new behaviours. It is important to explore ways that support can be found and elicited from those close to the people around them. For example, ask how a partner feels about them trying to become more active. If the people close to them understand their reasons for adopting new behaviours it is less likely they will be a negative influence or inadvertently create additional barriers. A person’s confidence is also likely to grow if the people around them are supportive and encouraging of them trying new behaviours.

One of the most successful and sustainable forms of physical activity was called ‘Mums on the Run.’ Given the barriers for exercise and needs for companionship for parents of pre-school children a group of up to 10 met weekly at a different person’s dwelling for coffee. Half the group went out for a jog/walk, leaving the others to enjoy a chat and look after the children. They switched roles after 30 mins and everyone’s needs were met at no cost.

3.7 Advanced Physical Activity Promotion

3.7.1 Why increase physical activity?

The general health benefits of increasing PA are shown on a Health Benefits card in the DoH HT handbook (p. 18). Clients may identify with these and other potential benefits when they see this list. These potential benefits may also be elicited using the Decision-Balance sheet.

Smokers are often aware of the link between smoking and weight management. One of the particularly relevant benefits of increasing PA may be to prevent weight gain once smoking is reduced or stopped.

3.7.2 Barriers to increasing physical activity?

It is not difficult to elicit a client’s perceived barriers to doing more PA in general. A more fruitful approach is to identify specific forms of PA and then seek to elicit perceived barriers to that dose and type of PA, which may be preferred. Negotiation with a client should go back and forth until ultimately goals are set which are specific attainable and realistic. This is another way

of saying, that the barriers are not insurmountable: They can be overcome. Setting goals which are unrealistic is inviting failure.

3.7.3 What support is available that can help a client to increase PA?

There are three ways of looking at supporting increases in PA:

1. Working with a client to change cognitions (such as benefits and barriers, and self-efficacy/confidence).
2. Build an empathetic relationship with the client, and encourage them to seek and gain support from others to achieve PA goals.
3. Direct clients to sources of information and opportunities for PA. Also, help a client to develop behavioural skills (e.g. self-monitoring using a pedometer) to enable them to achieve goals. To remove financial barriers to doing PA, participants in the EARS intervention will be offered incentives (e.g. free access to gyms).

3.7.4 Building on the DoH Health Trainer Handbook

The approaches for supporting clients to increase physical activity in the HT Handbook are largely sufficient for setting and evaluating goals, avoiding relapse and resetting goals over time. The HT may be able to extend initial discussions by asking clients to think about benefits and perceptions associated with different doses (frequency, intensity, duration, type, and timing). This may help to identify a client's preference for types of PA.

The HT Handbook does not consider when best to do PA. If the value of PA for regulating mood is recognised then a client may be helped to identify when it may be most valuable to engage in PA. The HT Handbook also does not consider how to support an increase in PA while reducing or stopping smoking at the same time. There is a view held by some that it may overload clients if too many behaviour changes are tackled at the same time, though others have suggested this does not have to be the case.

3.8 Physical Activity and Smoking Behaviour

3.8.1 Chronic physical activity and smoking cessation

Cross sectional data reveals that those who are more active are less likely to smoke, and smokers are typically less active as shown below. Does this mean that by increasing PA there

will be a tendency to reduce or stop smoking? And do smokers become more active when they reduce or stop smoking?

Several well conducted trials have considered what happens when a smoker who quits increases physical activity, with encouraging results. In one study, vigorous intensity structured (gym-based) exercise on three days a week over 15 weeks increased the number of female quitters at 12 months, relative to controls. But smokers may be more interested in moderate rather than vigorous activity.

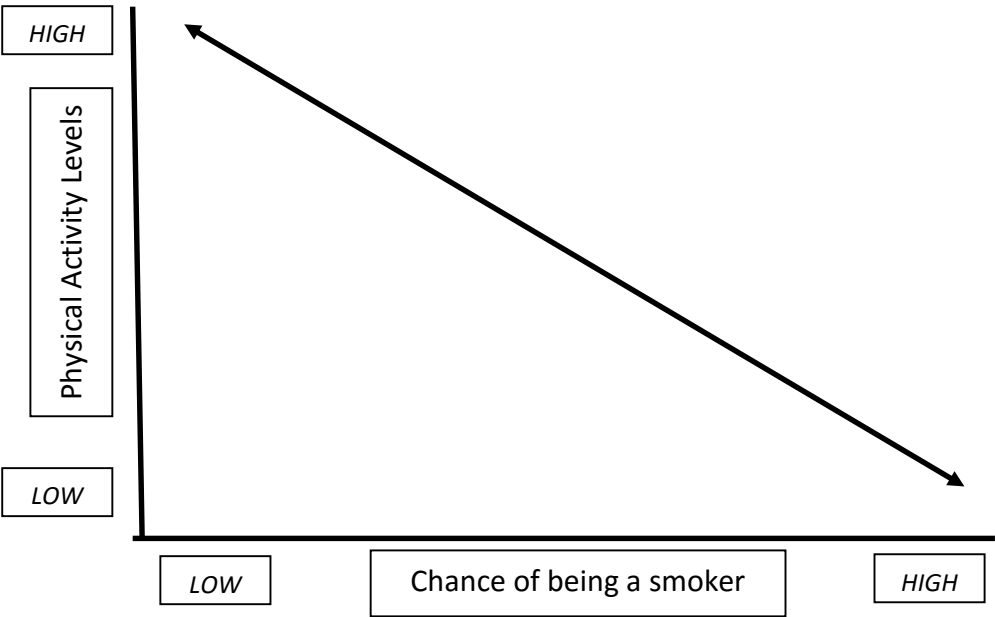


Fig. 7 Graphical representation of physical activity levels and the chance of being a smoker

3.8.2 How can physical activity help with smoking reduction and cessation?

Physical activity could influence smoking behaviour through either EXPLICIT or IMPLICIT processes. Smokers have told us that they deliberately use exercise such as going for a walk after a meal, to distract them from smoking when they would otherwise have smoked. Others have said that they were afraid of gaining weight so started doing more physical activity. Using physical activity as a method of directly compensating for the negative effects of smoking and quitting would be *explicit*.

In contrast, general increases in physical activity that may have indirect effects on smoking behaviour would be *implicit*. The table below lists some examples.

EXPLICIT processes	IMPLICIT processes
<ul style="list-style-type: none"> • Weight gain management. • Acute craving and tobacco withdrawal symptom management. • Focus on a increasing a positive behaviour (i.e. PA) rather than reducing or quitting smoking. 	<ul style="list-style-type: none"> • General enhanced mood and reduced depression and anxiety from PA, reduces urge to smoke. • General sense of enhanced mastery and self-perceptions, provides confidence to reduce smoking. • Reduced importance and reward from a cigarette. • Identity shift from a smoker to a non-smoker/exerciser. • Being in new environments where people don't smoke helps reduce conditioned response to smoke. • Money for sport and exercise participation may lead to a re-evaluation of money spent on cigarettes. • Feeling breathless when exercising may trigger fear appraisals about health status.

Table 3. Explicit and implicit processes

These processes all have implications for promoting PA to help smokers to reduce and quit smoking. Given that coping with cravings and withdrawal symptoms is one of the main reasons why smokers find it difficult to cut down or quit, using PA as a coping strategy may be important. Just generally increasing PA may also have valuable indirect benefits.

3.8.3 Acute physical activity management of cravings and withdrawal symptoms

Studies have consistently shown that during temporary smoking abstinence, when cravings are high, a short bout of PA (e.g. a brisk 15 min walk or 5 mins of seated isometric exercise) reduces cravings and withdrawal symptoms. The effects last beyond the exercise, for at least as long as the exercise itself.

When smoking cues are introduced, PA has been shown to limit the increases in cravings. Also, a session of PA delays ad libitum smoking. It would therefore appear appropriate for smokers to explicitly use short bouts of PA to aid smoking reduction and quitting.

If smoking is based on the need to relieve negative mood states then a single bout of physical activity can help control withdrawal symptoms and relieve cravings, as shown in the Figure below. Repeated exposure to physical activity, with enhanced mood, may help to increase a belief in the value of exercise for managing cravings and withdrawal symptoms.

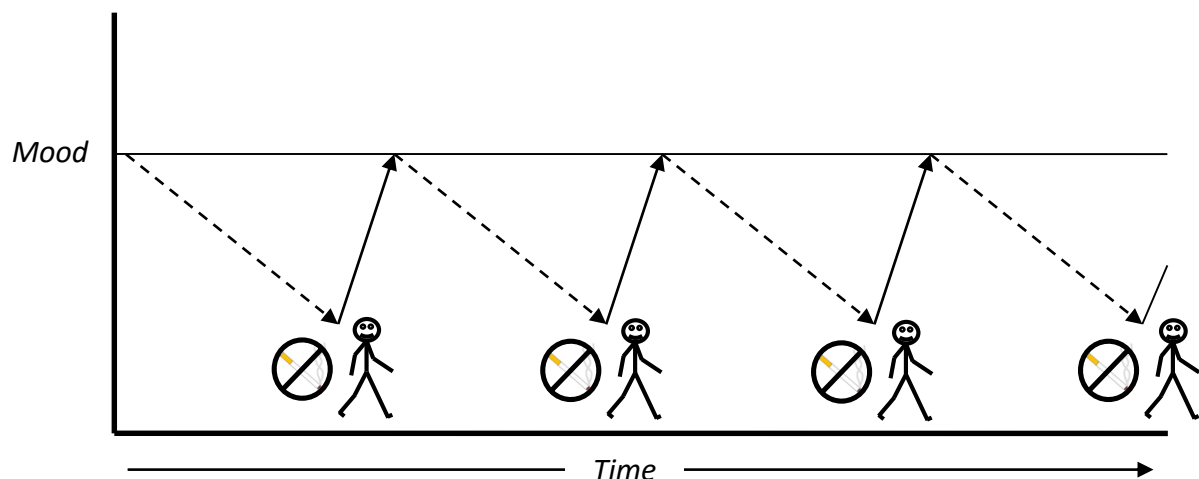


Fig.8 Graphical representation of negative mood states and smoking withdrawal symptoms

3.8.4 Physical activity and weight gain

After smoking cessation, smokers (and particularly women) experience an average of 5-7kg weight gain within a year of quitting. Fear of this weight gain prevents many people from

quitting. The effects on weight gain from smoking reduction are not known. Weight gain is a result of a slower metabolic rate without nicotine in the body and also emotional eating.

Increasing PA while cutting down (and quitting) may reduce weight gain not only by increased energy expenditure but also through improved control of energy intake (particularly via emotional eating).

3.9 Advanced elements of supporting behaviour change

As a HT working within EARS there is an opportunity to develop a more advanced understanding of how best to support behaviour change. In any attempt to support behaviour change there is a chance, indeed a high possibility of several things:

1. That clients may fear or experience failure to achieve goals.
2. That clients feel they are changing for someone else and not because they really want to.
3. That they are doing something which is not in line with what others feels they should do.

Such emotional responses minimise the chance of sustained engagement in an intervention, like the one planned in EARS, and also successful changes in behaviour.

In contrast, HT support that limits failure, encourages ownership and control of the behavioural change, and provides or facilitates opportunities for social support, may be more likely to result in sustained engagement in the intervention, and hence successful changes in behaviour.

Here we consider the value and process of promoting self-determined behaviour. Self Determination Theory (SDT) predicts that real shifts in behaviour result from satisfying three essential psychological needs (called the 3 Cs), which are having a sense of:

1. **Competence:** *When an individual feels capable to affect a desired behavioural outcome.*
2. **Control:** *When an individual feels to have a sense of personal choice in deciding what to do.*
3. **Companionship:** *When an individual feels secure within an environment while also fulfilling a need to feel connected to others.*

Goal setting is a core part of the role of the HT. It is very easy to see how goals could be set that undermine all these needs. A HT could also communicate in a way that undermines these needs.

So there are two key elements for developing advanced behaviour change skills:

1. Negotiate with clients to ensure the actions planned will satisfy these core needs (i.e. 3 Cs).
2. Communicate with clients in a way that will satisfy these core needs (i.e. 3 Cs).

3.9.1 Promoting physical activity to satisfy the 3 Cs

Supporting a client's increase in physical activity provides an opportunity for that individual to satisfy the three 'C's as follows:

COMPETENCE – By setting and achieving realistic goals an individual can build a sense of competence. [Equally, inappropriate goals can undermine a sense of competence, and clients with initially low self-efficacy may be quick to say, 'I told you so' when they experience failure.] Goals that are measurable provide an opportunity to gain a sense of achievement. Help the individual to identify these achievements and link them to the client's efforts. Short-term goals can help to build into long-term achievements and again, with reflection, provide a sense of achievement.

CONTROL – Through a client-centred approach, the client is involved in the goal setting process, and encouraged to link effort and success. Achievements linked to the role of the HT rather than the individual does not enhance a sense of control. Giving advice and information, when the individual could find this out for themselves can also undermine a sense of ownership and control or autonomy. The client should choose what activity to do, when, and where to do it.

COMPANIONSHIP – Quality PA experiences often involve other people, and the connection felt with others can be a strong motivator for that behaviour. The individual can also feel companionship in the environment they are in – a sense of belonging where they feel secure and competent.

Physical activity experiences which provide the individual with the satisfaction of these three Cs will see higher adherence rates. Activities which meet these needs for each individual will be vary greatly as different people put different values on different experiences. There is no 'one size fits all' activity, and tailoring action plans is crucial in developing an intrinsic motivation and sustained change.

3.10 Communicating with patients

Overall Aim: To maximise sustained behaviour change with a variable amount of the intervention.

Objectives

1. Achieve flexibility in the programme based on each individual's readiness to be introduced to and try participating in physical activity (PA) and reducing smoking – negotiate the type, intensity, duration, and frequency of activity the patient believes they can achieve.
2. Highlight and enable patients to access physical activity opportunities that minimise barriers, provide rewarding experiences, and result in sustainable physical activity.
3. Use compiled regional current information on physical activity opportunities matched to the patients' preferences and motivation/readiness to change.
4. Recognise the boundaries of the facilitator and be aware of risk assessment in case of the need of referral back to the GP (and informing trial coordinator).

Outcomes

- Enable patients to access physical activity opportunities that minimise barriers
- Provide rewarding experiences through negotiation & reinforcing positive events
- Achieve sustainable increases in physical activity (however subtle)
- Acquire self-regulatory skills in managing smoking cravings and withdrawal through the use of physical activity

Key principles

The following are key principles to follow when working with patients:

Allow choice

- Ensure that the patient understands the approach/model and acknowledge this approach makes sense to the patient
- Be flexible in assisting patients to decide upon activity
- Be aware that not all patients will embrace physical activity after initial session
- Be aware that any activity will be beneficial regardless of smoking habit and the patient may not achieve the government recommended levels of activity by the end of the contact time. But the physical activity patterns will have been established.

Develop rapport

- Listen to the patient. Make sure you have understood what they have said. Ask questions if you are not sure.
- Don't be judgemental. Respect their point of view. Do not disagree with a patient.
- Summarise what the patient has said. Don't assume you have understood what they have said. Make sure you repeat back what they have told you.

Avoid disagreement, lecturing or nagging

- Ask questions rather than give instructions
- It is a collaboration, make sure you work with your patient
- Never disagree or argue with a patient
- Don't nag, ask how you can help them achieve their plans
- Ask what stopped them achieving things this week

Make sure the patient understands the rationale

- Refer back to the patient's list of problems
- Make the link between their desire to cut down and the benefits of physical activity
- Repeat the rationale

Many of the above principles and techniques for developing rapport with clients are common sense and come naturally to a good communicator. They also overlap with an approach that you may have heard about called Motivational Interviewing (MI). It also links well the 3 Cs from Self-Determination Theory. The key thing is that in EARS the HT should adopt a client-centred communication style, which is compatible with the techniques and approaches described in the HT Handbook.

There may be times when clients request information and direction but, while this may have short term effects, it may not help sustainable changes in health behaviour.

The EARS intervention is not, however, about the effects of MI on smoking reduction and cessation, but we will borrow principles and techniques commonly used in MI.

The following 4 pages highlight some of the key aspects of MI.

3.10.1 Motivational interviewing

Definition of brief motivational interviewing: a directive, client-centred negotiating style for helping patients explore and resolve ambivalence about exercise (and other health behaviours) (Rollnick, 1992)

Motivational interviewing (MI) is a philosophical approach to behaviour change based around the idea that motivation to change behaviour will be enhanced, negotiated and directed by the interpersonal interaction between the patient and facilitator or professional. It is important to understand the philosophy behind motivational interviewing in order to correctly use techniques

and work through ambivalence with patients. As a patient centred approach, MI assists patients in articulating their concerns and arguments about behaviour change. MI is a flexible approach, with a number of strategies to choose from to match the level of readiness to change within each individual.

The goal of motivational interviewing is to help patients with their ambivalence towards changing behaviour through a series of techniques.

Ambivalence: Conflict between two different actions both having perceived costs and benefits. The main concept used is decision balance, weighing up the pros and cons of remaining inactive as compared to the pros and cons of being active.

Readiness to change: Determining where the patient is on a continuum of motivation and being ready to change their behaviour is also crucial for the facilitator to interpret. The readiness to change is an important factor to address in order to negotiate the patient through from not being prepared to change to already changing stage. Key questions to ask regarding this are ‘How important is it to you to change?’ and ‘How confident are you in making that change?’ These two questions will provide indication of the levels of readiness to change and are also extremely useful tools for you to use as the facilitator to encourage discussion around ambivalence.

Key principles

Roll with resistance – As facilitator it can be useful to offer new perspectives, but it is important not to impose them on the patient.

Express empathy – the key is to **actively** listen to the patient’s point of view and accept it even if you don’t approve of it.

Avoid argument – remember not to ‘label’ the patient as it encourages defensiveness and resistance from the patient.

Develop discrepancy – negotiate with patient to consider the consequences of their health behaviour and develop an awareness of the importance of the consequences.

Support self-efficacy – Assist patient through determining their own choices and understanding their own capabilities, pushing the boundaries progressively but only with their permission.

Skills you need as facilitator

- Asking open ended questions
- Use reflective listening
- Summarising/paraphrasing

Golden rules of Motivational Interviewing

- R: Roll with resistance
- E: Express empathy
- A: Avoid argument
- D: Develop discrepancy
- S: Support self-efficacy

Patients resistant to change: Why?

There are three main reasons why patients may be resistant to behaviour change. The first reason is that they may feel like they are having their control taken away from them. A good way to deal with this is to emphasise personal choice and control.

A second reason may be that you as the facilitator have misjudged or misinterpreted the patient's readiness to change, how important and/or how confident they are in changing. By revisiting these issues, the facilitator will have an opportunity to make a clearer judgment regarding these points.

The third reason may be that you as the facilitator have been a bit too confrontational, confronting force with force. This may occur when discussion around issues that the facilitator may consider straightforward in one instance turns out not to be so straightforward in the patient's view. To manage this, it's best to back off and essentially 'come alongside' the patient, not agreeing with them but changing tack and emphasising their own control and choice in the matter and negotiating the idea of change back into the discussion.

Menu of strategies

- Opening strategy: Lifestyle, stresses, health

- A typical day
- Assess motivation and confidence
- Good things and less good things about behaviour
- Providing information
- Future and present
- Exploring concerns
- Helping with decision making
- Modified barrier approach: reasons why do you want to and reasons why not
 - Explore reasons
 - Emphasise personal control and choice
 - Re-assess readiness, importance and confidence
- Social support – social benefits of exercise, group exercise

3.10.2 Counselling techniques

Breakdown tasks

People often tend to be discouraged by large tasks and any difficulties or problems seem overwhelming. The main strategy to prevent this is to break down large tasks into smaller tasks that are easier.

For some people, it might be important to suggest doing a limited number of these tasks during a week. For example, agree to perform steps 1-4 above in the first week.

For example, someone might suggest attending an exercise/dance class. A breakdown of this task might be as follows:

1. Find information on local classes
2. Identify sessions which could be attended
3. Speak to friend/s about attending with them (if appropriate)
4. Contact class to book/check availability
5. Obtain suitable footwear/clothing
6. Arrange transport to and from class
7. Agree a date for the first class

OR, someone might suggest walking more regularly. A breakdown of this task might be as follows:

1. Identify times in the week when a walk could take place
2. Locate possible walking routes
3. If transport is needed (rural walks) obtain information on travel options
4. Speak to friend/s about walking together (if appropriate)
5. Find suitable footwear and clothing
6. Find information on walking groups (if appropriate)
7. Plan a date for the first walk

Agree achievable goals

The goals for activity need to be agreed with the patient. It is a collaborative activity. People often set unrealistic goals that are too ambitious. If someone has not been exercising for some time they might set a target more appropriate for when they were more active in the past. Therefore make sure that you agree a realistic goal, particularly one that is easy to achieve. If people fail to achieve their goals then it can be discouraging.

Be aware that sometimes, people might achieve the goal but still come back and describe it as a disaster. This is because they have added on extra aims that you were not aware of at the time. For example, they might say “I went for a run around the park but had to stop twice”. The original agreed task was to run around the park but on return they have added an extra goal, to carry out the run without stopping. Remind the patient of the original aim and suggest that you include the additional aims in next week’s tasks.

Treat the activity as an experiment

Make sure you have elicited expectations about the activity that has been agreed. This is important to ensure that you agree with the patient what to achieve.

There are two aspects to the possible psychological benefit from exercise:

1. Enjoyment
2. Sense of achievement

If you treat the exercise as an experiment, you could suggest that the patient rates their expected enjoyment and sense of achievement before they carry out the agreed task. Then complete the same ratings after the task. Quite often, the patient either enjoys or has a greater sense of achievement than he or she expected. However, this is an experiment and everyone is different. It might also help them to choose the kind of things that they get the most benefit from.

4 The Intervention

Whilst the message being portrayed by the intervention is not one of smoking cessation but rather reduction, the main desired outcomes from the intervention are concerned with quitting and remaining abstinent. It is important to remember this and quitting should not be discussed with the participants unless they express a desire to do so (i.e. it is on their agenda, not the HT's agenda). The focus should always remain on reducing smoking behaviour and increasing physical activity.

4.1 Multiple behaviour change outline

Smokers who quit are generally advised not to change PA and diet at the same time by the Stop Smoking Service advisors. However, simultaneous multiple behaviour changes at the time of quitting does appear to be possible for some people, especially when PA is considered in terms of short bouts of daily activity, rather than structured, facility-based exercise on 2-3 occasions per week.

The goal of the EARS intervention is to support multiple behaviour changes in a way that limits mental overload, but uses PA to facilitate smoking reduction. The Figure below shows clearly the ideal scenario, and captures the dual aims of EARS.

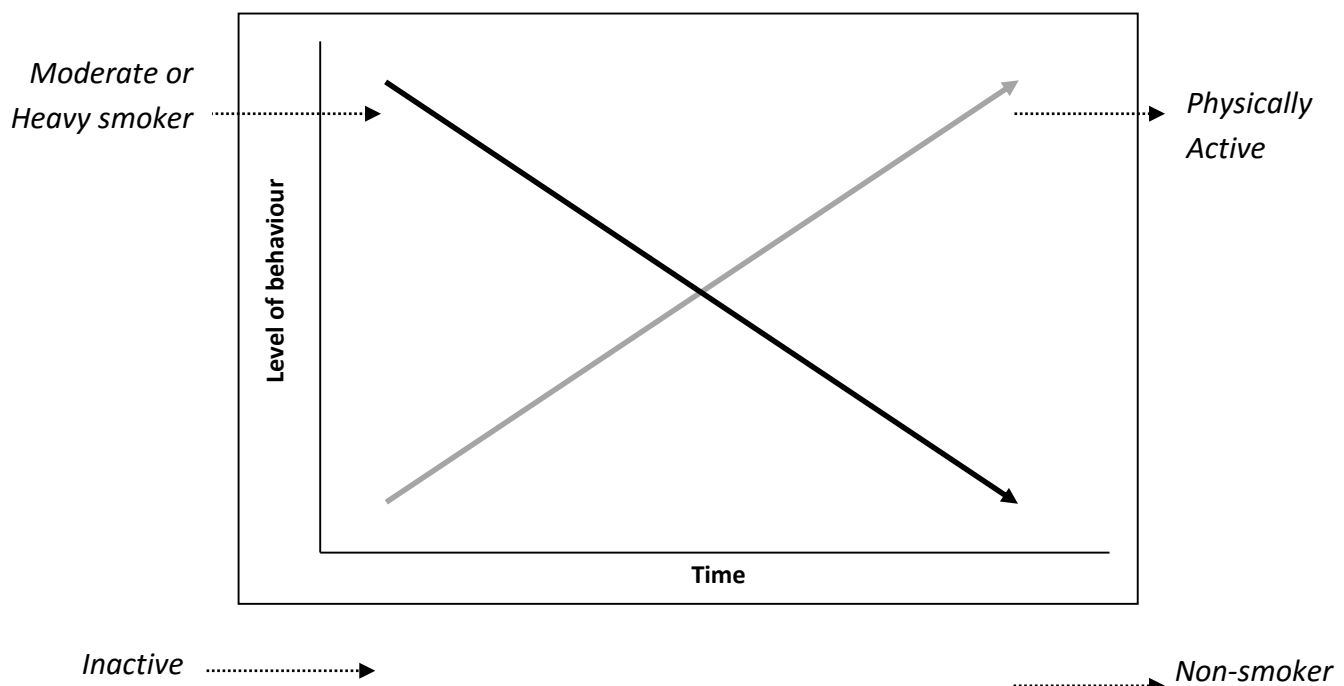


Fig 9 Graphical representation of ideal simultaneous multiple behaviour change

It is important that the participants appreciate how physical activity can impact on smoking; some clients will already accept this based on past experiences. Others will need more persuasion and experimentation. But it is a key component of EARS.

This Figure is available as a tool for generating initial discussions with smokers, alongside a Decision Balance sheet for the advantages and disadvantages of PA. Table 3 on p.32 also highlights how PA may explicitly and implicitly support smoking reduction and cessation, and these could be used as a tool to prompt clients.

4.2 Structure of the intervention

The EARS intervention sits inside a black box if you like, as shown in the Figure below. Ideally, we have inactive smokers coming in and active non-smokers going out, based on the efforts of the HT in what is a complex intervention.



Fig.10 Graphical representation of the EARS intervention as a black box

We would like to be able to describe it in a way that others could reproduce in future health services. But we accept that this may not be easy.

To be a truly client-centred intervention we need flexibility in how much support each smoker receives and when; it will not be a ‘one size fits all’ approach.

The study aims to determine what and how much support smokers want.

Nevertheless, we had to set a target for what support to offer and how to structure it, for the purposes of resource/staffing allocation. The EARS intervention will initially aim to consist of 2 face-to-face and 6 telephone communications, over 8 weeks, after baseline assessment and randomisation. We expect that many smokers will not want weekly contacts for 8 weeks. There will therefore be capacity to offer more to some people as required.

If at any point smokers express a desire to quit within those 8 weeks, they will be referred to a NHS SSS advisor for up to 6 weeks of support for quitting, using the usual pharmacotherapy and behavioural support. Six concurrent sessions will be delivered by the HT during this quit attempt to support the maintenance of PA?

4.3 Progression

Behaviour change is rarely a linear process, as the Figure on p. 11 of the HT Handbook shows. HT will help smokers to prepare for setbacks. Clients will increase PA and reduce smoking in a variable way, and could decide to quit at any point, if at all, within the initial 8 weeks of support. For one person, a 30 min walk on 5 days a week could be a great achievement that is worked towards over the 8 weeks, whereas others may accumulate shorter bouts within days. Reducing from 40 to 10 a day will require different progression compared with reducing from 20 to 10 a day.

Our early experiences of delivering the EARS intervention suggest that many smokers want to focus on smoking reduction initially, and already have ideas of which cigarettes to eliminate first. It then becomes a challenge to enhance any beliefs that physical activity maybe useful, as the remaining cigarettes pose a greater challenge to eliminate. HTs should not forget the focus of EARS on increasing physical activity.

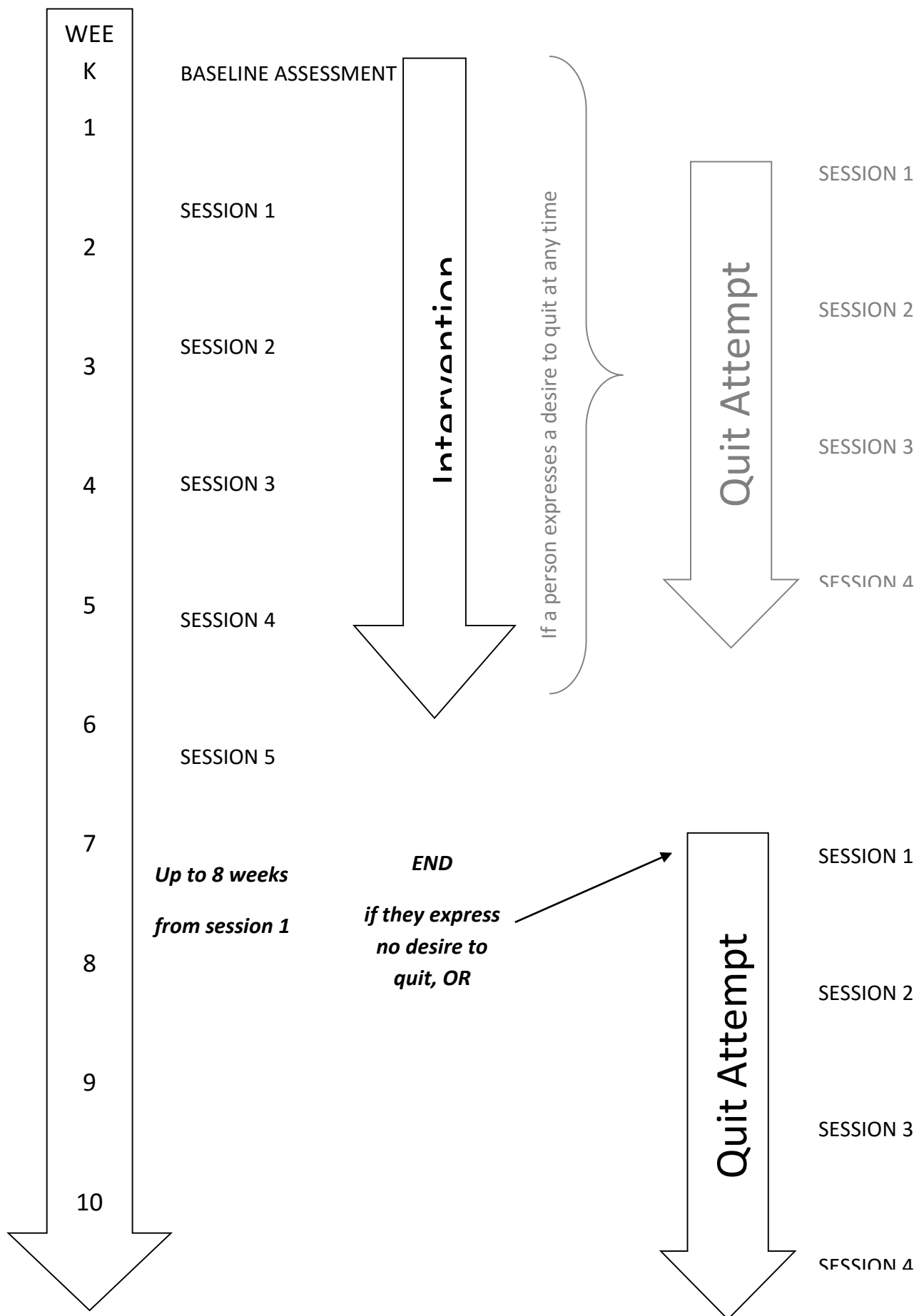


Fig. 11 Graphical representation of the EARS trial process in detail

4.3.1 Face-to-face meetings

Face-to-face meetings will take place in variety of locations acceptable to the participants. This could be in a **community location**, or in a **GP practice** or similar. The location will be negotiated with the participant. For the initial settings a community location or GP practice is preferable, and thereafter at the patient's home if the HT feels comfortable. It is the responsibility of the HT to book/arrange locations for meeting the participant. For any lone visits the LONE WORKER POLICY *must* be adhered to. See section 8.1.

The sessions can take place out of normal office hours in order to maximise participant attendance and retention, to be negotiated with the participant.

4.3.2 Telephone sessions

Each Health Trainer will be supplied with a mobile phone. This must be used for each contact made with the patient. The number should not be withheld and should be easily identifiable for the participant.

Again, the timing of the sessions should be flexible to suit the participant's needs.

Telephone sessions must be completed in a confidential manner where no one can over hear your conversation. If the participant has others around them that is their choice, check they are happy to continue, but the HT must be in a private space.

4.3.3 Keeping in contact

ALL contacts and attempted contacts with participants must be recorded. This is to be able to calculate how much of the planned intervention has been delivered and hence how much has it cost.

Each participant may have a different preference for ways of keeping contact. Email, text messaging, postal letters and telephone calls are all acceptable.

Every effort should be made to ensure successful contact – this could include postal reminders of appointments, text messages before calling or calling in the morning of an appointment as a gentle reminder. It is a frustrating waste of your time and project time if somebody does not

keep their appointment, but it *will* happen, so do not be disheartened and continue to make attempts to rearrange the appointment in line with the operating procedures.

5 Recruitment/Referral Procedures

An important part of the trial is to examine whether hard to reach smokers can be recruited into a smoking reduction trial such as EARS. The outlined recruitment strategy is to aim for 60 participants recruited through primary care (GP Practice lists) and 60 recruited through community based approaches (NHS SSS lists, outreach work etc).

Of the 120 participants recruited and randomised, over 12 months from March/April 2011, we would like approximately 75% (n=80) of the sample to be unemployed, receiving benefits, or in social class C2-E; 30% (n=36) from single parent families; 20% (n=24) with mental health problems, with some overlap between sub-groups. As the study progresses we will get a feel for whether we are meeting these targets, and hence if specific strategies need to be adopted to achieve them.

5.1 Primary Care Referral

Two GP practices have agreed to take part in the study:

**Marlborough Surgery, 1 Marlborough St., Devonport
PL1 4AE**

**Adelaide Surgery, 20 Adelaide St, Stonehouse
PL1 3JF**

With support from the Primary Care Research Network (PCRN) the practice lists will be systematically searched. GP practice lists contain information on smoking status: It is this information which will be used to identify potential participants who will be sent an invitation letter. To prevent the possibility of having too high an influx into the trial, this will be done in batches of 50 letters per practice every week. Depending on response/uptake rate this may change.

The study is adopting an 'opt out' approach in order to not exclude those with low literacy levels. After the letter is sent there are five possible next steps:

1. The participant contacts the HTs expressing an interest in taking part and is recruited.
2. The participant contacts the HTs expressing no desire to take part.

3. There is no contact from the participant within one week, then the HT makes contact by telephone and they are screened and if suitable recruited into the trial.
4. There is no contact from the participant within one week and the HT makes contact with the participant and they decline to take part.
5. There is no contact from the participant within one week and the HT fails to make contact with the participant.

5.2 Community Recruitment

Community recruitment approaches will be explored and developed throughout the trial. They will need to be well documented as reporting on effective community approaches is of great interest in a study of this nature. It is likely to consist of a very diverse range of approaches, including:

- NHS SSS Lists

NHS SSS possess lists of all those who have attempted to make an abrupt quit attempt using their service but have failed in the past. Invitation letters will be sent to those who meet the inclusion criteria, and the same 5 possible next steps as for the primary care referral will follow.

- Community Centres
- Community Events
- Outreach work
- Voluntary groups
- 'Health Champion' referral

The community recruitment approaches will be established in an exploratory way. Detailed records of the success of different type of contacts and approaches will be maintained.

6 Session by session

Overview of each session:

Session	Aim	Content (may be transient across sessions depending on individual progress)
1 (face-to-face)	<p>Introduction and assessment.</p> <p>Build rapport with patient.</p> <p>Explore patient beliefs about PA and smoking reduction.</p> <p>Enhance intrinsic motivation.</p> <p>Planning and goal setting.</p> <p>Enhance confidence for change</p>	<ol style="list-style-type: none"> 1. Discuss collaborative approach and explore nature of the patient's smoking and physical activity habits. 2. Build belief in the value of and importance of cutting down. 3. Explore pros and cons of change 4. Present 4 possible approaches to cutting down and ask participant to identify which is most appropriate to them. 5. Explore PA history, interests, pros and cons of different forms of PA. 6. Explore beliefs in PA as an aid to cutting down (explicitly – past experience?, and implicit effects) 7. Develop intrinsic motivation for PA and cutting down. 8. Present treatment structure, flexibility of sessions, organization of sessions. 9. Explore tasks for next session, self-monitoring with weekly worksheet. 10. This content can extend into and be repeated in subsequent sessions depending upon patient's readiness to change.

<p>2 (phone call)</p>	<p>Building commitment to increase PA and reduce smoking. Planning and goal setting. Provide feedback.</p>	<ol style="list-style-type: none"> 1. Review progress (tasks, new tasks, changes and barriers) 2. Work through pros and cons of increasing and maintaining PA. 3. Encourage self-monitoring with a weekly worksheet to identify PA level, and strengthen perceived links between PA and smoking levels. 4. Support client in planning and goal setting for PA and continued reduction. 5. Signpost client to PA opportunities if needed. 6. Encourage a different reduction approach if the first approach has been unsuccessful. 7. Revise strategy and plans if necessary (phone vs in person session). 8. This content can extend into and be repeated in subsequent sessions depending upon patient's readiness to change.
<p>3 (phone call)</p>	<p>Discussion of progress, outcomes and barriers. Support psychological needs associated with PA (the three Cs). Encourage belief in value of PA as a tool for coping with reduction. Provide feedback.</p>	<ol style="list-style-type: none"> 1. Assess progress with goals set at last session 2. Facilitating PA experience – explore ways to build competence, autonomy and relatedness in an enjoyable way 3. Discuss completion of goals, what they found easy or difficult and why (autonomy) 4. Discussion of 'barriers and facilitators' 5. Discuss revision of goals, plan new goals (competence) 6. Discuss how to progress with new goals to increase interaction with significant others (relatedness)

4 (phone call)	Revise progress, discuss medium/long term goals. Continue to support psychological needs Encourage belief in value of PA.	<ol style="list-style-type: none"> 1. Review previous goals, reflect on achievements and plan new goals – building a sense of competence 2. Explore ways to build a sense of control (self-regulation) over PA behaviour and mood. 3. Explore ways to build relatedness or companionship through PA
5 (phone call)	Discuss progress/changes in well-being. Barrier management and continuing activity. Establish/maintain (or progress to) PA and reduction targets	<ol style="list-style-type: none"> 1. Promote self-regulatory skills and ownership of PA decisions/choices and reflect on progress on reduction 2. Encourage quality social opportunities (companionship) through PA participation. 3. Maintain use of goal setting (worksheets if used) 4. Discuss potential strategies to help maintain activity.
6 (phone call)	Review maintenance strategies. Reinforcing activity and revision.	<ol style="list-style-type: none"> 1. Highlight patients' control over PA choices and effects on mood and smoking behaviour. 2. Reinforce any changes in self-confidence related to PA and smoking reduction. 3. Review progress and explore how to manage relapse. 4. Encourage reflection on situations which illicit undesirable behaviour (increases smoking) and explore ways to deal with these

7 (phone call)	Review maintenance strategies. Reflect on achievements. Consider long term maintenance/goals.	<ol style="list-style-type: none"> 1. Reinforce positive changes in behaviour to this point 2. Reflect on the benefits gained from changing behaviour 3. Emphasise distance travelled and achievements made, no matter how small 4. Begin to discuss potential strategies for long term maintenance (eg identifying relapse)
8 (face-to-face)	Final discussions. Exit strategy.	<ol style="list-style-type: none"> 1. Discuss triggers/cues to changes in PA and smoking behaviour 2. Explore management and modification to strategies 3. Consider positive experiences and how to re-engage in PA if relapse or smoking increases.
<p><i>The sessions during a quit attempt may begin at any time up to session 8 or after session 8 if the express a desire to quit during that session. Although the main outcome measure (expired air CO) is taken 4 weeks post quit, 6 weeks of support will be provided to allow for lag time between expressing a desire to quit and accessing NHS SSS support and then setting a quit date. There is an element of uncertainty n these timings and flexibility is essential.</i></p>		
START OF QUIT ATTEMPT 1 (face-to-face)	Goal setting. Support psychological and behavioural needs. Coping with cravings	<ol style="list-style-type: none"> 1. Discuss explicit use of PA as a coping strategy for cravings 2. Build link between inactivity and elevated cravings (weekly worksheets on cravings and PA) 3. Revise activity goals in line with quit attempt
QUIT ATTEMPT 2 (face-to-face)	Review of progress. Revision of goals. Building three 'c's of activity	<ol style="list-style-type: none"> 1. Review progress of goals – what was easy what was hard. 2. Explore situations and behaviours which elevated cravings and strategies to cope with these in future 3. Reflect on nature and quality of PA (is it satisfying the three 'c's of Control, Competence, and Companionship?)

QUIT ATTEMPT 3 (face-to-face)	Review of progress. Revision of goals. Building three 'c's of activity Overcoming barriers	<ol style="list-style-type: none"> 1. Review progress of goals – what was easy what was hard. 2. Explore situations and behaviours which elevated cravings and strategies to cope with these in future 3. Reflect on nature and quality of PA (is it satisfying the three 'c's of Control, Competence, and Companionship?)
QUIT ATTEMPT 4 (face-to-face)	Review of progress. Revision of goals. Building three 'c's of activity Overcoming barriers. Identifying smoking cues.	<ol style="list-style-type: none"> 1. Review progress of goals – what was easy what was hard. 2. Explore situations and behaviours which elevated cravings and strategies to cope with these in future 3. Reflect on nature and quality of PA (is it satisfying the three 'c's of Control, Competence, and Companionship?)
QUIT ATTEMPT 5 (face-to-face)	Review of progress. Revision of goals. Building three 'c's of activity Overcoming barriers. Identifying smoking cues. Relapse prevention planning	<ol style="list-style-type: none"> 1. Review progress of goals – what was easy what was hard. 2. Explore situations and behaviours which elevated cravings and strategies to cope with these in future 3. Reflect on nature and quality of PA (is it satisfying the three 'c's of Control, Competence, and Companionship?)
QUIT ATTEMPT 6 (face-to-face)	Review of progress. Revision of goals. Building three 'c's of activity Overcoming barriers. Identifying smoking cues. Relapse prevention planning	<ol style="list-style-type: none"> 1. Review progress of goals – what was easy what was hard. 2. Explore situations and behaviours which elevated cravings and strategies to cope with these in future 3. Reflect on nature and quality of PA (is it satisfying the three 'c's of Control, Competence, and Companionship?)

7 Appendices

7.1 Reflective checklists

7.1.1 Session 1 checklist

1ST SESSION NOTES

What are you expecting to get out of the study / why are you taking part?

Go through smoking diary

Typical day

Why do you think you smoke?

Which cigarettes do you enjoy throughout the day?

Have you tried to quit before?

What were the benefits of quitting?

What was hard about quitting?

What do you think the benefits of reducing will be?

Is there anything that you think will be difficult about reducing?

Importance of reducing 0 – 10

Confidence to reduce 0 – 10

Look at strategies

Set goals to reduce 10-25%

How confident are you at achieving this? 0 – 10

Do you mind if we talk about PA now

What does PA mean to you ?

Is there anything you used to like doing?

Any ideas about how physical activity may help with you reduce the amount you smoke.

Discuss wearing a pedometer

Summarise

Arrange a time to ring next week and explain will need to collect data.

7.1.2 Session 2-8 checklist



Exercise Assisted Reduction for Smoking (EARS)

SESSION NOTES

Practice Participant ID	
Health Trainer	

DATE:

TIME:

LOCATION:

PATIENT'S SELF REPORTED PHYSICAL ACTIVITY

PATIENT'S SELF REPORTED SMOKING REDUCTION

GOAL PLANNING AND SETTING

SUPPORT AND INVOLVEMENT OF SIGNIFICANT OTHERS

Carbon Monoxide reading :

Time of last cigarette:

Notes:

7.2 Problem-solving worksheets

7.2.1 Physical activity worksheet

Physical Activity	
Benefits of doing physical activity	Problems with doing physical activity

7.2.2 Cutting down on smoking worksheet

Cutting Down on Smoking

Benefits of smoking less	Problems with smoking less

7.2.3 Coping strategies worksheet

Coping strategies for high risk situations

There are certain situations where you might find yourself particularly wanting a cigarette and where you might find it difficult to resist the urge to smoke.

Use the form below to identify situations that you might find difficult and what you could do to overcome them.

Identify smoking triggers and try to avoid them – Triggers may be anything from driving, friends who smoke or smoking paraphernalia such as ash trays.

Think positive. This can strengthen your will power and increase your confidence. Some people say to themselves that they want to save money or improve their health more than they want the cigarette.

SITUATION	POSSIBLE SOLUTIONS

TRIGGERS	POSSIBLE SOLUTIONS

Positive statement that you could make:

Cravings

Time of day	How long it lasts	How strong it was	What you did to deal with the cravings

7.2.5 Typical day & reasons for smoking worksheet

Typical day & reasons for smoking			
Time of day	Cigarettes smoked	Enjoyed 😊 Not enjoyed 😞 Not bothered 😐	Why did you smoke?
6am – 8am			
8am – 10am			
10am – 12pm			
12pm – 2pm			
2pm – 4pm			
4pm – 6pm			
6pm – 8pm			
8pm – 10pm			
10pm – 12am			
12am – 2am			
2am – 4am			
4am – 6am			

7.3.1 Physical activity diary

PHYSICAL ACTIVITY DIARY

Use this diary to record any physical activity you do throughout the week – this includes things like walking, using the stairs instead of the lift or carrying light loads as well as sports and going to the gym. Write down how long you do these activities for.

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Morning							
Afternoon							
Evening							
How energised did you feel after the activity (on a scale of 1 to 10 – 1 being not at all and 10 being you felt great)							

7.3.2 Smoking diary

SMOKING DIARY

Use this diary to record how many cigarettes you smoke throughout the week – writing in the diary each day will be easier than trying to remember how many you smoked at the end of the week.

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Morning							
Afternoon							
Evening							
How satisfying was the cigarette? (on a scale of 1-10) (10 being satisfying and 1 being that you felt you needed another one)							

7.4.1 Benefits of reducing smoking

Benefits of Reducing Smoking

- To improve health
- Reduces the discolouration of teeth
- Food tastes better
- Saves money
- Breathing becomes easier
- To gain a sense of control
- Increased energy levels

7.4.2 Benefits of quitting

Benefits of quitting

Within 20 minutes of last cigarette:

- Blood pressure drops to normal
- Pulse rate drops to normal rate
- Body temperature of hands and feet increases to normal

After 8 hours:

- Carbon monoxide level in blood drops to normal
- Oxygen level in blood increases to normal

After 48 hours:

- Nerve endings start to regrow
- Ability to smell and taste improves

After 72 hours:

- Bronchial tubes relax, making breathing easier
- Lung capacity increases

Two weeks to Three months:

- Circulation improves
- Walking becomes easier
- Lung function increases up to 30%

One to nine months:

- Coughing, sinus congestion, fatigue, shortness of breath decrease
- Cilia regrow in lungs increasing ability to handle mucus, clean the lungs and reduce infection, fewer colds and bronchitis

One year:

- 50% reduction in cardiovascular risk

Five years:

- Lung cancer death rate for average smoker halves

Ten years:

- Pre – cancerous cells are replaced with normal cells
- Risks of other cancers, like those of the mouth, oesophagus, bladder, kidney and pancreas decrease
- Risk of coronary artery disease the same as non – smoker

Ten to Fifteen years:

- Overall mortality of the ex – smoker equals that of the non- smoker

General points:

- Non-smokers are good role models for their children.
- Non – smokers have healthier babies and children.
- Non – smokers live 5 – 8 years longer.
- Non – smokers spend more time with their grandchildren.

Smoking and Physical Activity

Cutting down helps improve breathing and therefore helps people to become more active. Increasing activity may:

- Reduce an urge to smoke as the period between cigarettes increases
- Reduce withdrawal symptoms such as stress and anxiety, low mood, irritability, restlessness and hunger
- Serves as a distraction and becomes a new interest to replace the need for cigarettes
- Help to prevent weight gain
- Help to see yourself as a physically active person rather than as a smoker
- Becoming more active may improve sleeping patterns

PHYSICAL ACTIVITY

- Going for a 10 minute walk 3 times a day could reduce your cravings throughout the day.
- Physical activity works as a substitute for nicotine – taking your mind off having a cigarette. It has been shown that people will leave it longer before having the next cigarette.
- It is a powerful aid to reduce the urges to smoke.
- Physical activity is also known to actively reduce stress, can help lift your spirits and clear your mind.

HOW ACTIVE ARE YOU

STEPS PER DAY	ACTIVITY RATING
<5,000	INACTIVE/SEDENTARY
5,000 - 7499	LOW ACTIVE
7,500 – 9,999	SOMEWHAT ACTIVE
>= 10,000	ACTIVE
>12,500	HIGHLY ACTIVE

7.5.6 How much does smoking cost you?

HOW MUCH DOES SMOKING COST YOU?

HOW MUCH COULD YOU SAVE IF YOU REDUCE THE AMOUNT YOU SMOKE?

Number of cigarettes smoked per day	£ per day	Number of cigarettes smoked per week	£ per week	Number of cigarettes smoked per month	£ per month	Number of cigarettes smoked per year	£ per year
5	£1.60	35	£11.20	152	£48.64	1,825	£584.00
10	£3.20	70	£22.40	304	£97.28	3,650	£1,168.00
15	£4.80	105	£33.60	456	£145.92	5,475	£1,752.00
20	£6.40	140	£44.80	608	£194.56	7,300	£2,336.00
30	£9.60	210	£67.20	912	£291.84	10,900	£3,488.00
40	£12.80	280	£89.60	1216	£389.12	14,600	£4,672.00

Based on one packet of cigarettes costing £6.31. Each cigarette costing £0.32 (32 pence). May 2011

BARRIERS TO CUTTING DOWN

Putting on weight	Nicotine increases metabolism and suppresses appetite, so when someone stops smoking they will gain, on average, 7KG in 12 months. There is no evidence for what effects smoking reduction has on weight. Try drinking lots of water and increasing physical activity can really help.
Becoming irritable and stressed	Nicotine cravings between cigarettes make you feel stressed and anxious, so when you smoke and give yourself a nicotine hit you feel calmer. Discuss and list coping strategies.
My friends and family smoke	
Lack of confidence	Set yourself realistic goals
Not being able to cope with cravings	
Like to go out for a drink with friends	
Boredom	

7.5.8 Barriers to exercise

BARRIERS TO EXERCISE

Barrier	Solution	Questions to ask
I don't have time	Take a look at how you really spend each day – chances are you can find time for a 30 minute physical activity break once a day. Try to wake up a half hour earlier and take the dog for a walk, getting off a stop earlier when taking the bus, climbing the stairs instead of taking the lift. You don't have to do 30 minutes at once, try building physical activity into your daily routine in periods of at least 10 minutes each. You may find by reducing your smoking you find you have more time. Try to schedule times for exercise and stick to them.	Think about how long you take to have a cigarette x how many cigarettes reduces. Physical activity has shown to increase energy levels so you find you can do more things in the same amount of time.
Exercise is boring	There's so much to choose from, including just putting more zest into your normal daily activities. Try a social activity you can try with a friend or family member. Try something you enjoyed when you were younger or something new. Set yourself an activity challenge or raise money for a	Maybe exercise in the past has been boring, but this time think about how you can make it more enjoyable. Seeing the benefits of physical activity can be fun and rewarding.
		What is it about it that you find boring? – opportunity to highlight alternatives (agree-build rapport)

	charity. Think about what types of physical activity appeal to you. Listen to your favourite music.		
I don't have the right clothes	You don't need to buy new clothes. You can do things like walking, stair climbing, housework, gardening in your normal clothes.		
I'm too tired	Try to do some physical activity during the time of day when you have the most energy and remember small bouts of physical activity all add up.	You will probably notice that being more physically active actually gives you more energy – being inactive is what can make people feel tired. Regular activity will help you sleep better at night.	Think back to a time when you've complete some physical activity. How awake did you feel immediately afterwards?
I'm not very fit	Many activities such as a short walk, using the stairs and heavy housework do not require high levels of fitness. You can gradually increase how far you walk and increase your pace, which will in turn increase your level of fitness.	If you want to try something more vigorous then discuss this with your doctor first.	
It's too hot/cold/rainy	Exercise indoors such as doing some home exercises, climbing stairs, exercise DVD, dance to music, ironing, tidy cupboards, clean house thoroughly. Take a walk around the Mall. Play	Since you can't do your normal activities, you will have to try something new and different!	

	activity games with the kids. Play on the wii.		
Physical activity is expensive	It doesn't have to be. Walking is free, so is household chores and gardening and washing your car. Use whatever you have available, many household items can be effective aids. Use soup cans or water bottles as dumbbells, use the edge of a sturdy chair for tricep dips, use stairs for step ups. Do activities with your family. Plan a weekend walk, evening walks, softball games.	Look for convenient, free or inexpensive resources in your community.	
If I take time to be physically active it's taking time away from my family	You're never too old and it's never too late to become physically active. Start doing small bouts of activity and build on this.	Evidence has shown that frail, elderly people have successfully built their strength through simple activities in a short time.	
I don't have anybody to look after my children	Do something physically active with your children. Children need physical activity too, no matter what age. Go for a walk, dance to music, play in the park, play ball games. Take it in turns with a friend to watch the children if you want to go for a swim or jog.		
I would be embarrassed if anybody saw me exercising	Ask yourself what really matters. You will be doing something positive for your health and that	You many even inspire others to get physically active.	

	is something to be proud of. Invite a friend or neighbour to join you.		
I'm already very active	Perhaps you could try some other activities or even something new.	That's great! You are probably already aware of the many benefits, but you can still benefit from using physical activity as a coping mechanism as you reduce your smoking.	

7.5.9 Coping strategies for different situations

Coping strategies for different situations

An average craving will last about 5-7 minutes. They become less intense as you become more accustomed to not smoking as much.

SITUATION	POSSIBLE SOLUTIONS
Having a cigarette after a meal	<ul style="list-style-type: none"> • Clean your teeth after eating • Go for a walk even if it's only for 5 minutes • Do the washing up as soon as you finish your meal.
Having a cigarette when drinking a cup of coffee/tea	<ul style="list-style-type: none"> • Try drinking something different for example a glass of water, fruit juice or a herbal tea instead.
Having a cigarette when drinking alcohol	<ul style="list-style-type: none"> • Alcohol undermines your decision <u>NOT</u> to smoke. • Try drinking low alcoholic drinks • Avoid going to the pub or parties until you feel more confident.
Avoid difficult situations	<ul style="list-style-type: none"> • Try to avoid tense situations • Avoid arguments at home • Try To avoid being around smokers in the first instance.
Develop a support network	<ul style="list-style-type: none"> • Tell someone that you are cutting down so that they can support and encourage you. • Buy yourself rewards with the money you save.
Having a cigarette when bored.	<ul style="list-style-type: none"> • Make a drink • Go out for a walk or any other physical activity • Housework • Phone a friend • Do some isometric exercises e for example see how many step ups you can do in a minute, press ups against a wall, use a study chair to do some tricep dips • Read a book • Take up a hobby – needlework, woodwork
Having a cigarette when stressed or irritable.	<ul style="list-style-type: none"> • Go for a walk as this will help symptoms such as stress, anxiety, low mood and irritability. Walking produces chemicals in the brain that are associated with feeling better.
Smoking when driving the car	<ul style="list-style-type: none"> • Keeping mints or gum in the car which may help to keep cravings to a minimum
Having a cigarette when talking on the phone	<ul style="list-style-type: none"> • Keep a pen and paper nearby instead for doodling rather than smoking

Identify smoking triggers and try to avoid them – Triggers may be anything from driving, friends that smoke or post meal rituals.

Think of things you can do when a craving comes on and make a list.

Think positive. This can strengthen your will power and increase your confidence. Some people have said they say to themselves that they have chosen to cut down and list the benefits they want to achieve.

WORKING OUT CIGARETTE EQUIVALENTS

Cigars



- One small size cigar is equivalent to approximately: **1.5 cigarettes.**
- One medium size cigar is equivalent to approximately: **2 cigarettes.**
- One large size cigar is equivalent to approximately: **4 cigarettes.**

Pipes



One bowl of tobacco is roughly equivalent to 2.5 cigarettes. Take the total number of bowls of tobacco smoked per day and multiply by 2.5, for example:

- 8 bowls of tobacco is equivalent to 20 cigarettes.
- 4 bowls of tobacco is equivalent to 10 cigarettes.

Roll-Your-Own (roll ups)



If a person can't tell you how many roll-ups they smoke per day the following may be of assistance.

Each 25gms (1oz) of tobacco is approximately equivalent to 50 cigarettes. The smoker needs to be asked how many ounces of tobacco they smoke per week, then apply the following formula which has been seen to give a fairly accurate guide to the cigarette equivalents smoked.

25gms tobacco (1oz)	smoked p/w =	50 cigarettes/7 days	= approx.	7 cigarettes/day.
50gms tobacco (2oz)	smoked p/w =	100 cigarettes/7 days	= approx.	14 cigarettes/day.
75gms tobacco (3oz)	smoked p/w =	150 cigarettes/7 days	= approx.	21 cigarettes/day.
100gms tobacco (4oz)	smoked p/w =	200 cigarettes/7 days	= approx.	28 cigarettes/day.
125gms tobacco (5oz)	smoked p/w =	250 cigarettes/7 days	= approx.	35 cigarettes/day.
150gms tobacco (6oz)	smoked p/w =	300 cigarettes/7 days	= approx.	42 cigarettes/day.

7.5.11 NRT Guide

Nicotine Replacement Therapy

There are 6 Products of Nicotine Replacement Therapy available on prescription or to buy over the counter

Generally you should NOT smoke at the same time as using any of the Nicotine Replacement Products

Correct use of NRT can double your chance of quitting successfully

Using NRT in pregnancy is considered to be safer than continuing to smoke for the mother and the baby, and can be used after consultation with a Health Care Professional if it is considered that the woman would be unable to quit smoking without its use

- If you have any concerns, anxiety or
- Use the patches for at least 3 months, 4-6 weeks at the high strength and 4-6 weeks at the low strength

Side effects

Occasional skin irritation, if it side effects with any of the NRT products, please consult the prescriber

Always read the enclosed patient information leaflet

Nicotine Replacement Patches

- Available in 16hr and 24hr preparations
- Available in high, medium and low strength
- The 16hr patch is applied in the morning and removed when going to bed
- The 24hr patch is worn through the night, if it is your habit to have a cigarette within an hour of getting up you need to consider this patch
- Apply a new patch to a new site each day to clean, dry, unbroken and preferably hairless skin. If it does not resolve in a few days then try a different brand or a different form of NRT
- Headaches
- Dizziness
- Nausea

NRT Gum

- Available in 2 strengths 2mg and 4mg and in different flavours
- If it is your habit to smoke within an hour of getting up you require the 4mg strength
- Each piece should be chewed VERY slowly until the flavour is felt in the mouth the gum should then be rested in the cheek until it is required again
- Each piece should last about 30 minutes
- Use 10-15 pieces a day on demand for a 3 month period – reducing the number of pieces used over the last 4-6 weeks

NRT Lozenges

- Available in 1mg, 2mg and 4mg strengths
- Use the 4mg strength if you need to smoke within 1 hour of getting up
- Allow the lozenge to dissolve in the mouth over a period of 20-30 minutes
- Do not eat or drink at the same time as using a lozenge
- A minimum of 9 and a maximum of 15 lozenges can be used each day over a period of 3 months – gradually reducing the number used over the last month

NRT Sublingual Tablets

- Available in 2mg strength
- Place the microtab under the tongue and allow to dissolve over 20 minutes – do not chew, suck or swallow
- Use 15-20 microtabs each day for 3 months – gradually reduce the number used over the last month

NRT Inhalator

- The inhalator has the appearance of a cigarette holder
- Useful for those who miss the ritual of the hand to mouth movement
- Use shallow or deep puffing in response to demand
- Each cartridge will last about 90 minutes with 6-12 cartridges being used each day for about 8 weeks, gradually reducing the number of cartridges used over 4-6 weeks
- The inhalator needs to be at about body temperature to work effectively – it is less effective at a cold temperature

Side effects of all oral preparations

- Cough
- Throat irritation
- Wind/Gastric disturbance
- Stinging in the mouth
- Continued use after 6 months – change to using the patches for 3 months – 1 month at high, 1 month at medium and 1 month at low strength
- NRT Gum has an unpleasant taste if chewed too quickly
- Avoid fizzy drinks prior to or during use

NRT Nasal Spray

- Fastest acting Nicotine Replacement Therapy – very useful for the very heavy smoker
- One puff into each nostril every hour as required for 2 months, gradually reducing the number of puffs used over the last month

Side effects

- Nasal irritation
- Watery eyes
- Throat irritation
- Headaches
- Dizziness

The nasal spray should not be used when driving or operating machinery.

7.5.12 Champix guide

Champix

- Champix was launched in the UK in December 2006. It is a non nicotine treatment that has been found to be beneficial in helping the well motivated smoker to quit successfully
- One tablet (1mg) is taken twice daily following a 1 week of stepped introduction (days 1-3, 0.5mg daily; days 4-7, 0.5mg twice daily). It is taken for a total of 12 weeks
- A quit date to stop smoking is set in the 2nd week after starting Champix
- It is advisable to take Champix with or just after food
- For maximum benefit it is advisable to complete the three month course

Contra-indicators to the use of Champix

Anyone with any of the following conditions should **NOT** use Champix

- Known reaction to any of the ingredients
- Pregnancy/breast feeding
- Under 18

Precautions

- Severe kidney disease
- May cause some drowsiness so may affect ability to drive or operate machines
- There is no experience of using it in patients with epilepsy
- Patients with certain mental health conditions should be closely monitored when stopping smoking

Possible side effects

- Nausea (very common but usually mild)
- Sleep disturbance
- Abnormal dreams
- Headache and nausea
- Increased appetite
- Dizziness
- Dry mouth
- Constipation
- Diarrhoea
- Abdominal discomfort
- Heart burn
- Wind
- Tiredness

Notify your doctor or stop smoking adviser if you have any unusual side effects

7.5.13 Zyban Guide

Zyban

Zyban is a non nicotine treatment that has been found to be beneficial in helping the well motivated smoker to quit successfully.

- It was originally used as an anti-depressant in America but was found to have the effect of reducing the desire to smoke – it is not a miracle cure but it helps the well motivated person
- One tablet is taken daily for six days, then increased to one tablet in the morning and one in the evening. There must always be 8 hours between each dose taken.
- A quit date to stop smoking is set in the 2nd week after starting Zyban
- Swallow tablets whole, do not suck or chew
- For maximum benefit complete the two month course
- Zyban must ONLY be used under medical supervision

Absolute Contra-indicators to use of Zyban

Anyone with any of the following conditions should NOT use Zyban

- Under 18 years old
- Epilepsy or fitting
- Previous reaction to Zyban
- Any current or previous history of brain tumour
- Any current or previous eating disorder eg Bulimia or Anorexia
- Any history of cirrhosis of the liver
- Any history of alcohol abuse
- Any history of Bipolar or manic depression
- Any current recent use of MAOI drugs (Monoamine-oxidase inhibitors)
- Pregnancy, planning a pregnancy or breast feeding

Anyone with the following conditions or on the following medication may use Zyban but with GREAT CAUTION strictly under a doctors supervision and possibly at a lower dose

- Diabetics on hypoglycaemic drugs or insulin
- Any history of previous head injury
- Whilst taking sedating antihistamines eg Piriton, Dimotane, Nytol or Panadol Night
- Whilst on Steroids either tablets or injections
- Certain Antibiotics eg Ofloxacin, Levofloxacin or Norfloxacin
- Whilst taking Tramadol (a strong pain killer)
- Whilst taking any stimulants or slimming medication
- Certain Antidepressants eg Clozapine, Risperidone, Thioridazine or Olanzapine
- Anyone on Theophylline
- Whilst taking Anti-malarial medication

Always inform your doctor of all medication that you are taking both those prescribed and those bought over the counter

Very common side effects

- Sleep disturbance

Common side effects

- Dry mouth
- Headaches
- Constipation
- Gastro-intestinal pain
- Nausea
- Vomiting
- Tremor
- Dizziness
- Depression
- Agitation
- Anxiety
- Rash
- Itchy skin
- Sweating
- Fever
- Taste Disorder
- Concentration Disturbance
- Notify your doctor if you have any of the side effects

Uncommon side effects

- Chest Pain
- Shortness of breath
- Numbness
- Palpitations
- High Blood Pressure
- Flushing
- Confusion
- Loss of Appetite
- Ringing in the ears
- Visual disturbance

Rare side effects

- Aggressive behaviour
- Fainting or blackouts
- Fitting
- Hallucinations
- Anaphylaxis

If any of these side effects occur STOP the drug immediately and notify your doctor

Appendix 5 Process fidelity scales

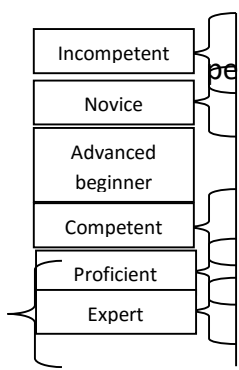
The rating scale

The present six point scale (i.e. a 0-6 Likert scale) extends from (0) where the HT did not deliver the intervention element appropriately - either they didn't do it well or didn't do it sufficiently (low fidelity) to (6) where there is the element is delivered appropriately (high fidelity). Thus the scale assesses a composite of adherence to the intended intervention method and skill of the HT. To aid with the rating of items, an outline of the key features of each item is provided at the top of each section. A description of the various rating criteria is given in Figure 1. The examples are intended to be used as useful guidelines only, providing illustrative anchor points, rather than prescriptive scoring criteria.

Adjusting for the presence of participant difficulties

Adjustments may be needed when participant difficulties are evident (e.g. excessive avoidance or resistance). In such circumstances, the rater needs to assess the HT's therapeutic skills in the application of the methods. Even though the HT may not facilitate change, credit should be given for demonstrating appropriate skillful interaction.

Competence level* Scoring Examples

	0	Absence of feature and /or highly inappropriate performance
	1	Minimal use of feature and /or inappropriate performance,
	2	Evidence of competence, but numerous problems
	3	Competent, but some problems or inconsistencies
	4	Good features, but minor problems or inconsistencies
	5	Very good features, minimal problems or inconsistencies
	6	Excellent performance

* The scale incorporates the Dreyfus system (Dreyfus, 1989) for denoting competence. Please note that the 'top marks' (i.e. near the 'expert' end of the continuum) are reserved for those HTs demonstrating highly effective skills, particularly in the face of difficulties (i.e. smokers with high resistance to change; high levels of emotional expression; and complex situational barriers). Please note that there are 5 competence levels but six potential scores.

When rating the item, you should first identify whether some of the ‘Key Features’ are present. If the HT includes most of the key features and uses them appropriately (i.e. misses few relevant opportunities to use them and delivers them well), the HT should be rated very highly. It is important to remember that the scoring profile for this scale should approximate to a normal distribution (i.e. mid-point 3), with relatively few scoring at the extremes.

Dreyfus, H. L. (1989). The Dreyfus model of skill acquisition. In J. Burke (ed.) Competency based education and training. London: Falmer Press.

ITEM 1: ACTIVE PARTICIPANT INVOLVEMENT

Key features: The HT should encourage the smoker to be actively involved in the consultation. The idea is to maximise the smoker’s autonomy as the main agent of change, developing intrinsic rather than extrinsic motivation, and encouraging her /him to be the person coming up with ideas for improving the situation. However, the smoker should not be allowed to ramble in an unstructured way and the consultation should be guided. A collaborative /shared decision-making style is appropriate and the HT may share his /her own expertise and ideas, using techniques such as elicit-provide- elicit (below). Overall, the smoker should be increasingly empowered to take control of her /his smoking and related physical activity behaviour. Interactions should be encouraging, respectful and non-judgemental (the opposite of a didactic, telling or persuading style of interaction). The smoker should ideally talk for at least half of the time. The interaction should also be *individually tailored* to the participant’s specific information needs, beliefs, motivations and barriers. The HT should engender a clear sense of warmth, genuineness and empathy (within professional boundaries).

Intervention techniques: OARS (Open questions, Affirmation, Reflective listening, Summaries). Reflective listening may include simple reflections of content but may also be more sophisticated (e.g. amplified reflection; reflection with a twist) and used to direct the conversation or highlight key strengths or barriers. The Ask-Tell-Discuss (elicit-provide-elicit) technique should be used to exchange information (e.g. to address misconceptions, or offer helpful new information). The above empathy-building techniques and Individual tailoring should be used throughout the consultations - from the initial consultation through action-planning through to review /maintenance sessions.

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the HT has delivered this intervention process

- | | |
|---|--|
| 0 | Absence of active participant involvement techniques. A highly didactic /practitioner-led or 'lecturing' style of interaction, which may increase or sustain client's resistance |
| 1 | Minimal participant involvement or use of active participant involvement techniques. The practitioner dominates the discussion |
| 2 | Appropriate use of participant involvement techniques, but not frequent enough. The practitioner sometimes dominates the discussion |
| 3 | Appropriate and frequent use of participant involvement techniques. Teamwork evident, but some difficulties in content or method of delivery |
| 4 | Appropriate and frequent use of participant involvement techniques. Minor problems evident (e.g. some reflection opportunities missed) |
| 5 | Highly appropriate and regular use of participant involvement techniques, facilitating shared understanding and decision making. Minimal problems |
| 6 | Excellent / expert use of participant involvement techniques throughout all consultations. A clear sense of collaborative alliance is developed. |

ITEM 2: MOTIVATION-BUILDING FOR CUTTING DOWN /QUITTING

Key features: The HT should work with the smoker to explore initial beliefs about cutting down, and quitting (importance and confidence, triggers for smoking). The smoker's motivation and confidence for cutting down is built up/enhanced through the exchange of information and techniques to assess and enhance motivation – i.e. to enhance the perceived benefits (importance) of cutting down /quitting and confidence (self-efficacy) to take the actions needed.

Intervention techniques: OARS (Open questions, Affirmation, Reflective listening, Summaries) should be used specifically to explore current and past smoking behaviour, the pros and cons of cutting down and to develop discrepancies between current behaviour and desired behaviour (or outcomes). The decisional balance technique or 0-10 questions may be used to explore importance and confidence. Information should be exchanged on the pros and cons of cutting down and this and other techniques (exploring possible futures; discussing past quitting attempts) should be used to explore barriers and possible solutions to increase confidence about cutting down /quitting. Motivation-building should ideally happen around the start of the intervention process, although it can be further explored and reinforced at later

(action-planning, review and maintenance) stages. Establishing self-rewards or incentives (e.g. saving money in a jar, planning rewards) may be part of the process for maintaining motivation.

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the HT has delivered this intervention process. NB: achieving a strong motivation is not necessary to score highly here – the aim is to explore motivation sufficiently to allow the client to be able to make an informed choice (which may be not to make any changes at this point in time)

- | | |
|---|---|
| 0 | Absence (or very poor delivery) of motivation-building techniques. Motivation to cut down or quit smoking is assumed or not discussed |
| 1 | Minimal use of (or poor delivery of) motivation-building techniques. Minimal exploration of either reasons for change or confidence about making changes. |
| 2 | Some use of motivation-building techniques, but the exploration of motivation to cut down or quit is not of sufficient depth or detail |
| 3 | Appropriate use of motivation-building techniques. However, some difficulties evident (e.g. moving on to change talk before motivation is fully established) |
| 4 | Appropriate and frequent use of motivation-building techniques relating to cutting down or quitting smoking. Minor problems evident (e.g. some inconsistencies) |
| 5 | Highly appropriate and sufficient use of motivation-building techniques, facilitating a clear understanding of reasons for change and confidence issues. Minimal problems |
| 6 | Excellent / expert use of motivation-building techniques, facilitating a clear understanding of reasons for change and confidence issues. No real problems |

ITEM 3: MOTIVATION-BUILDING FOR PHYSICAL ACTIVITY

Key features: The HT should work with the smoker to introduce PA as an aid to cutting down and quitting. They should explore initial beliefs about *increasing physical activity* (importance and confidence). The smoker's motivation and confidence for introducing new physical activity behaviours should be built up through the exchange of information and techniques to assess and enhance motivation – i.e. to enhance the smoker's perceived benefits and usefulness (importance) of physical activity and confidence (self-efficacy) to take the actions needed.

Intervention techniques: OARS (Open questions, Affirmation, Reflective listening, Summaries) should be used specifically to explore current and past physical activity behaviour, the pros and cons of increasing PA and to develop discrepancies between current behaviour and desired behaviour (or outcomes). The decisional balance technique or 0-10 questions may be used to explore importance and confidence. Information should be exchanged on the pros and cons of physical activity and this and other techniques (exploring possible futures; discussing past quitting attempts) should be used to explore barriers and possible solutions to adopting PA strategies /increasing PA. Motivation-building should ideally happen around the start of the intervention process, although it can be further explored and reinforced at later (action-planning, review and maintenance) stages.

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the HT has delivered this intervention process. NB: achieving a strong motivation or any changes is not necessary to score highly – the aim is to explore motivation sufficiently to allow the client to be able to make an informed choice about whether to change or not.

- | | |
|---|---|
| 0 | Absence (or very poor delivery) of motivation-building techniques. Motivation to adopt physical activity strategies is assumed or not discussed |
| 1 | Minimal use of (or poor delivery of) motivation-building techniques. Minimal exploration of either reasons for change or confidence about making changes. |
| 2 | Some use of motivation-building techniques, but the exploration of motivation for physical activity is not of sufficient depth or detail |
| 3 | Appropriate use of motivation-building techniques. However, some difficulties evident (e.g. moving on to change talk before motivation is fully established) |
| 4 | Appropriate and frequent use of motivation-building techniques relating to physical activity. Minor problems evident (e.g. some inconsistencies) |
| 5 | Highly appropriate and sufficient use of motivation-building techniques, facilitating a clear understanding of reasons for change and confidence issues. Minimal problems |
| 6 | Excellent / expert use of motivation-building techniques, facilitating a clear understanding of reasons for change and confidence issues. No real problems |

ITEM 4: SET GOALS AND DISCUSS STRATEGIES TO REDUCE SMOKING

Key features: The HT should work with the smoker to discuss a range of strategies for reducing the amount of cigarettes smoked. They should agree a verbal plan of action, seeking to make this as specific as possible. They should discuss the use of self-monitoring to keep track of progress.

Intervention techniques: Goal-setting (with gradual /graded progression), Action Planning, Self-Monitoring, Deconditioning strategies. Any or all of the four distinct EARS strategies for cutting down (based on breaking the conditioned /automated link between smoking and reward and replacing this with consciously mediated strategies) may be presented and discussed. The action plan should normally be made verbally, but the HT should seek to make this as specific as possible in terms of “What, Where, When and Who with” and making the goal as SMART (Specific, Measurable, Achievable, Relevant and Time-related) as possible. The HT should introduce and discuss with the smoker the usefulness of self-monitoring of behaviours (number of cigarettes smoked, pattern of use). A specific plan for self-monitoring should be included in the action plan. The HT may also encourage self-monitoring of the contexts (social or environmental or emotional circumstances) in which problems /relapses might occur. Pre-empting and thinking of solutions for possible problems (making a coping plan) is also appropriate here and may involve the use of other recognised behaviour change techniques (e.g. engaging social support, stress-management).

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the HT has delivered this intervention process

- | | |
|---|--|
| 0 | Absence (or very poor delivery) of action-planning techniques or discussion of smoking-reduction strategies |
| 1 | Minimal use (or poor delivery) of action-planning techniques or discussion of smoking-reduction strategies |
| 2 | Some use of action-planning techniques or discussion of smoking-reduction strategies, but not in sufficient depth or detail |
| 3 | Appropriate use of action-planning techniques and discussion of smoking-reduction strategies. However, some difficulties evident (e.g. not setting up self-monitoring; plan generated more by the HT than by the smoker) |
| 4 | Appropriate use of action-planning techniques and discussion of strategies. Minor problems evident (e.g. the plan is a bit less specific than it could be) |
| 5 | Highly appropriate and sufficient use of action-planning techniques and discussion of smoking-reduction strategies. Minimal problems |
| 6 | Excellent / expert use of action-planning techniques and discussion of smoking-reduction strategies. No real problems |

ITEM 5: SET GOALS AND DISCUSS STRATEGIES TO SET GOALS TO INCREASE PHYSICAL ACTIVITY

Key features: The HT should work with the smoker to discuss ideas for introducing new physical activities that might help to reduce smoking. They should agree a verbal plan of action, seeking to make this as specific as possible. They should discuss the use of self-monitoring to keep track of progress, including offering a pedometer as a means of monitoring walking activity if appropriate.

Intervention techniques: Goal-setting (with gradual /graded progression), Action Planning, Self-Monitoring. Ideas for introducing relevant physical activities should be discussed. The action plan should normally be made verbally, but the HT should seek to make this as specific as possible in terms of “What, Where, When and Who with” and making the goal as SMART (Specific, Measurable, Achievable, Relevant and Time-related) as possible. The HT should introduce and discuss with the smoker the usefulness of self-monitoring of behaviours (using memory, a diary and /or a pedometer). A specific plan for self-monitoring should be included in the action plan. Pre-empting and thinking of solutions for possible problems (making a coping plan) is also appropriate here and may involve the use of other recognised behaviour change techniques (e.g. establishing prompts or cues to do physical activity).

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the HT has delivered this intervention process

- | | |
|---|---|
| 0 | Absence (or very poor delivery) of action-planning techniques in relation to physical activity |
| 1 | Minimal use (or poor delivery) of action-planning techniques |
| 2 | Some use of action-planning techniques relating to physical activity, but not in sufficient depth or detail |
| 3 | Appropriate use of action-planning techniques. However, some difficulties evident (e.g. no self-monitoring; plan generated more by the HT than by the smoker) |
| 4 | Appropriate use of action-planning techniques relating to physical activity. Minor problems evident (e.g. the plan is a bit less specific than it could be) |
| 5 | Highly appropriate and sufficient use of action-planning techniques. Minimal problems |
| 6 | Excellent / expert use of action-planning techniques relating to physical activity. No real problems |

ITEM 6: REVIEW EFFORTS TO CUT DOWN SMOKING / PROBLEM-SOLVING

Key features: The HT should work with the smoker to reflect on progress with *smoking reduction*. The HT should affirm /reinforce any successes. The smoker and HT should discuss any setbacks (reframing to normalise them, identifying barriers and exploring ways to overcome them). The HT and smoker should then set new targets (possibly including making an attempt to quit).

Intervention techniques: Use of OARS (Open questions, Affirmation, Reflective listening, Summaries) specifically to reinforce successes, to discuss setbacks, to identify barriers (including social or environmental contexts which increase cravings) and explore ways to overcome them (problem-solving). Reframing should be used to normalise setbacks. Goals /action plans should then be reviewed. There may also be some reflection on, and reinforcement of, the smoker's skills in avoiding or managing relapse (building skills and self-efficacy). Problem-solving may involve the use of other recognised behaviour change techniques (e.g. engaging social support, stress-management).

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the HT has delivered this intervention process

- | | |
|---|--|
| 0 | Absence (or very poor delivery) of progress review or problem-solving techniques in relation to smoking reduction |
| 1 | Minimal use (or poor delivery) of progress review or problem-solving techniques |
| 2 | Some use of progress review and problem-solving techniques in relation to smoking reduction, but lacking sufficient depth or detail |
| 3 | Appropriate use of progress review and problem-solving techniques. However, some difficulties evident (e.g. not reinforcing successes, providing rather than eliciting possible solutions to problems) |
| 4 | Appropriate and frequent use of progress review and problem-solving techniques in relation to smoking reduction. Minor problems evident |
| 5 | Highly appropriate and sufficient use of progress review and problem-solving techniques, facilitating a clear understanding of the current situation and how to move forward. Minimal problems |
| 6 | Excellent / expert use of progress review and problem-solving techniques in relation to smoking reduction, facilitating a clear understanding of the current situation and how to move forward. No real problems |

ITEM 7: REVIEW EFFORTS TO INCREASE PHYSICAL ACTIVITY /PROBLEM-SOLVING

Key features: The HT should work with the smoker to reflect on *progress with introducing relevant physical activities*. The HT should affirm /reinforce any successes. The smoker and HT should discuss any setbacks (reframing to normalise them, identifying barriers and exploring ways to overcome them). The HT and smoker should then revise the smokers PA-related goals.

Intervention techniques: Use of OARS (Open questions, Affirmation, Reflective listening, Summaries) specifically to reinforce successes, to discuss setbacks, to identify barriers and explore ways to overcome them (problem-solving). Reframing should be used to normalise setbacks. Goals /action plans should then be reviewed. There may also be some reflection on, and reinforcement of, the smoker's skills in avoiding or managing relapse (building skills and self-efficacy).

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the HT has delivered this intervention process

- | | |
|---|--|
| 0 | Absence (or very poor delivery) of progress review or problem-solving techniques in relation to the physical activity component of the intervention |
| 1 | Minimal use (or poor delivery) of progress review or problem-solving techniques |
| 2 | Some use of progress review and problem-solving techniques in relation to physical activity, but lacking sufficient depth or detail |
| 3 | Appropriate use of progress review and problem-solving techniques. However, some difficulties evident (e.g. not reinforcing successes, providing rather than eliciting possible solutions to problems) |
| 4 | Appropriate and frequent use of progress review and problem-solving techniques in relation to physical activity. Minor problems evident |
| 5 | Highly appropriate and sufficient use of progress review and problem-solving techniques, facilitating a clear understanding of the current situation and how to move forward. Minimal problems |
| 6 | Excellent / expert use of progress review and problem-solving techniques in relation to physical activity, facilitating a clear understanding of the current situation and how to move forward. No real problems |

ITEM 8: INTEGRATION OF CONCEPTS: BUILDING AN ASSOCIATION BETWEEN PA AND SMOKING REDUCTION

Key features: The HT should work with the smoker to specifically help her /him gain an appreciation of the relationship between physical activity and smoking. A clear rationale should be presented for how PA might be relevant to reducing smoking (e.g. as a distraction, as a way to reduce withdrawal symptoms such as stress or cravings, as a way to prevent weight gain when reducing smoking). However, both explicit processes (explanations) and implicit processes (learning from experience, disrupting usual patterns of smoking behaviour; reductions in withdrawal symptoms that the smoker is not consciously aware of) should be facilitated by the HT.

Intervention techniques:

Explicit integration techniques might include a) developing (ideally using the Ask-Tell-Discuss information-exchange technique) an appropriate conceptualisation or rationale for increasing PA as an aid to reducing smoking b) setting up an experiment (to do some extra PA) and encouraging self-monitoring of links between physical activity and cigarette cravings, as well as on cigarette use. Implicit techniques might include a) setting up an experiment to see if it helps reduce smoking, with monitoring only of outcomes (cigarette use) and without trying to make a conscious link between PA and strength of cravings. Review of experiences with using PA and its impact on cravings or smoking behaviour may also be used in later sessions.

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the HT has delivered this intervention process

- | | |
|---|--|
| 0 | The absence (or very poor delivery) of techniques to link PA to cravings or amount smoked |
| 1 | Minimal use (or poor delivery) of techniques to link PA to cravings or amount smoked. No clear rationale linking PA to smoking reduction is understood by the client |
| 2 | Some use of techniques to link PA to cravings or amount of cigarettes smoked, but not of sufficient depth or detail. Only a limited rationale linking PA to smoking reduction is understood by the client. |
| 3 | Appropriate use of techniques to link PA to cravings or amount of cigarettes smoked. The rationale is at least partly understood by the client. Some difficulties evident (e.g. not addressing misconceptions, not using Ask-Tell-Discuss) |
| 4 | Appropriate use of techniques to link PA to cravings or amount of cigarettes smoked. The rationale is understood by the client. Minor problems evident (e.g. minor inconsistencies) |

- 5 Highly appropriate use of techniques to link PA to cravings or amount of cigarettes smoked. The rationale is well developed and understood. Minimal problems
- 6 Excellent / expert use of techniques to link PA to cravings or amount of cigarettes smoked. The rationale is well developed and understood. No real problems

ITEM 9: IDENTIFY AND REINFORCE ANY IDENTITY SHIFTS TOWARDS BEING A MORE 'HEALTHY PERSON' OR 'HEALTHY LIVING'

Key features: The HT should pick up on any opportunity to reflect or reinforce statements that the smoker makes relating to becoming or wanting to become a healthier person in general.

Intervention techniques: Open questions, Affirmation, Reflective listening. Reflective listening may include simple reflections of content but may also be more sophisticated (e.g. amplified reflection; reflection with a twist) and used to direct the conversation or highlight key changes in thinking that may generalise to a change in the client's self-concept or identity, particularly with regard to being a healthy person or living a healthy lifestyle.

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the HT has delivered this intervention process. It is recognised that there may only be a few, if any opportunities to deliver this aspect of the intervention. Hence, we expect scores to be relatively low for this item.

- 0 Absence (or very poor delivery) of identity-building interactions
- 1 Minimal (or poorly delivered) identity-building interaction
- 2 Some identity-building interaction
- 3 Several examples of identity-building interaction. However, some difficulties evident (e.g. missed opportunities, talking at odds with the participant)
- 4 Appropriate use of identity-building interactions, taking almost all opportunities. Minor problems evident
- 5 Highly appropriate and sufficient use of identity-building interactions. Minimal problems
- 6 Excellent / expert use of identity-building interactions. No real problems

ITEM 10: ENGAGING SOCIAL SUPPORT AND MANAGING SOCIAL INFLUENCES ON SMOKING REDUCTION

Key features: The HT should encourage the smoker to engage social support (to assist on making or carrying out plans) or manage social influences *on smoking behaviour*. Social support can be informational (helping to make plans, providing ideas), emotional (not putting pressure on the person to smoke/accepting their decision to cut down or quit), or practical (e.g. helping to monitor progress).

Intervention techniques: Open questions, Affirmation, Reflective listening and Summaries may be used to explore social influences and to identify possible problems and solutions relating to social influences.

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the HT has delivered this intervention process

- | | |
|---|--|
| 0 | Absence (or very poor delivery) of interactions around engaging social support or managing social influences on smoking behaviour |
| 1 | Minimal (or poorly delivered) interaction around engaging social support or managing social influences |
| 2 | Some interaction around engaging social support or managing social influences on smoking behaviour, but not in sufficient depth or detail |
| 3 | Several examples of interaction around engaging social support or managing social influences. However, some difficulties evident (e.g. missed opportunities, talking at odds with the participant) |
| 4 | Appropriate use of interactions to engage social support or manage social influences on smoking behaviour, taking almost all opportunities. Minor problems evident |
| 5 | Highly appropriate and sufficient use of interactions to engage social support or manage social influences. Minimal problems |
| 6 | Excellent / expert use of interactions to engage social support or manage social influences on smoking behaviour. No real problems |

ITEM 11: ENGAGING SOCIAL SUPPORT AND MANAGING SOCIAL INFLUENCES ON PHYSICAL ACTIVITY

Key features: The HT should encourage the smoker to engage social support (to assist on making or carrying out plans) or manage social influences on *physical activity*. Social support can be informational (helping to make plans, providing ideas), emotional (not putting pressure on the person to smoke/accepting their decision to cut down or quit), or practical (e.g. helping to monitor progress).

Intervention techniques: Open questions, Affirmation, Reflective listening and Summaries may be used to explore social influences and to identify possible problems and solutions relating to social influences.

Mark with an 'X' on the vertical line, using whole and half numbers, the level to which you think the HT has delivered this intervention process

- | | |
|---|--|
| 0 | Absence (or very poor delivery) of interactions around engaging social support or managing social influences on physical activity |
| 1 | Minimal (or poorly delivered) interactions around engaging social support or managing social influences |
| 2 | Some interaction around engaging social support or managing social influences on physical activity, but not in sufficient depth or detail |
| 3 | Several examples of interaction around engaging social support or managing social influences. However, some difficulties evident (e.g. missed opportunities, talking at odds with the participant) |
| 4 | Appropriate use of interactions to engage social support or manage social influences on physical activity, taking almost all opportunities. Minor problems evident |
| 5 | Highly appropriate and sufficient use of interactions to engage social support or manage social influences. Minimal problems |
| 6 | Excellent / expert use of interactions to engage social support or manage social influences on physical activity. No real problems |

ITEM 12: REFERRAL TO SMOKING CESSATION SERVICES

Was the issue of making an attempt to stop smoking raised and the response appropriately addressed (i.e. if desired, to make a referral to NHS SSS)?

Yes ☐

No ☐

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